Attachment B:

Example of Bio-Rad's Unified Labeling

BIO-RAD

# Lyphochek® Tumor Marker Control Levels 1 and 2

Bio-Rad's Unified Labeling

REF 580 Bilevel 6 x 2 mL | CE 0197 | IVD For In Vitro Diagnostic Use | EXP 2005-11-30 | LOT 44110 Level 1 44111 Level 2 44112

ENGLISH

## INTENDED USE

Lyphochek Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert

## SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices Two levels of control are available to allow performance monitoring within the clinical range.

## REAGENT

This product is prepared from human serum with added constituents of human and animal origin, pure chemicals and stabilizers The control is provided in lyophilized form for increased stability

## STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is reconstituted, all analytes will be stable for 14 days when stored tightly capped at 2 to 8°C, with the following exceptions: Ferritin and CA 27 29 will be stable for 6 days. ACTH, Free PSA, PSA, and Calcitonin should be assayed immediately following reconstitution For optimum precision of Ferritin, allow vial to equilibrate for a minimum of 2 hours prior to assay

After reconstituting and freezing the control, all analytes will be stable for 30 days when stored tightly capped at –10 to –20°C Once thawed, do not refreeze the control; discard remaining material

## RECONSTITUTION

Using a volumetric pipet, reconstitute each vial with 2 0 mL of distilled or deionized water Replace the stopper and allow the control to stand at room temperature (18 to 25°C) for approximately 15 minutes, swirling occasionally Before sampling, gently invert the vial several times to ensure homogeneity

## PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services

## LIMITATIONS

1 This product should not be used past the expiration date.

2 If there is evidence of microbial contamination or excessive turbidity in the reconstituted control, discard the vial.

3. This product is not intended for use as a standard

## ASSIGNMENT OF VALUES

The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control Individual laboratory means should fall within the corresponding acceptable range, however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications it is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides

## SPECIFIC PERFORMANCE CHARACTERISTICS

This product is a freeze-dried product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values, the control requires proper storage and handling as described

DEUTSCH

## VORGESEHENER VERWENDUNGSZWECK

Die Lyphochek Tumor Marker Control ist ein Qualitätskontrollserum fur die quantitative Bestimmung der in dieser Packungsbeilage angegebenen Analyte, mit Zielwertangaben

## EINLEITUNG UND ZUSAMMENFASSUNG

Die Verwendung entsprechender Kontrollmaterialien dient der objektiven Beurteilung der Qualitat von im Labor durchgefuhrten Untersuchungen und ist ein unerlässlicher Bestandteil der guten Laborpraxis. Die zwei Level dieser Kontrolle ermoglichen eine umfassende Qualitatssicherung uber den gesamten klinisch relevanten Bereich.

## REAGENZ

Dieses Produkt wurde aus Humanserum hergestellt und enthalt Zusatze menschlichen und tierischen Ursprungs sowie reine Chemikalien und Stabilisatoren Die Kontrolle wurde zur Verbesserung der Stabilitat lyophilisiert

## LAGERUNG UND HALTBARKEIT

Dieses Produkt ist bis zum angegebenen Haltbarkeitsdatum stabil, wenn es ungeoffnet bei 2 bis 8°C gelagert wird. Nach Rekonstitution der Kontrolle sind alle Analyte 14 Tage stabil, sofern die Kontrolle dicht verschlossen bei 2 bis 8°C aufbewahrt wird Ausnahmen Ferritin und CA 27 29 sind 6 Tage stabil ACTH, freies PSA, PSA und Calcitonin mussen sofort nach der Rekonstitution bestimmt werden Um eine optimale Prazision bei der Ferritinbestimmung zu erzielen, sollte das Fläschchen mindestens 2 Stunden vor der Bestimmung equilibriert werden

Nach Rekonstitution und Einfrieren der Kontrolle sind alle Analyte 30 Tage stabil, sofern das Material dicht verschlossen bei –10°C bis –20°C aufbewahrt wird Die Kontrolle nach dem Auftauen nicht erneut einfrieren; restliches Material verwerfen

## REKONSTITUTION

In jedes Fläschchen mit einer Vollpipette genau 2,0 ml destilliertes oder deionisiertes Wasser pipettieren Mit dem Stopfen verschließen und die Kontrolle etwa 15 Minuten bei Raumtemperatur (18°C bis 25°C) stehen lassen; gelegentlich schwenken. Vor Entnahme einer Probe den Inhalt des Flaschchens vorsichtig durchmischen, um die Homogenitat sicherzustellen.

## HANDHABUNG

Das Produkt ist genau wie eine Patientenprobe zu behandeln und in Übereinstimmung mit den Vorschriften des Gerate-, Kit- oder Reagenzherstellers anzuwenden.

Die Entsorgung aller Abfälle ist nach den geltenden ortlichen Bestimmungen vorzunehmen Falls die Verpackung beschadigt ist, nehmen Sie bitte Kontakt zur Bio-Rad-Niederlassung auf.

## EINSCHRÄNKUNGEN

1. Dieses Produkt nach Ablauf des Haltbarkeitsdatums nicht mehr verwenden.
2. Bei Anzeichen einer mikrobiellen Kontamination oder einer starken Trübung der rekonstituierten Kontrolle ist das Fläschchen zu verwerfen
3 Dieses Produkt ist nicht zur Verwendung als Standard geeignet

## WERTEERMITTLUNG

Die in dieser Packungsbeilage angegebenen Mittelwerte stammen aus Vielfachbestimmungen und gelten speziell fur diese Produktcharge Die angegebenen Tests wurden vom Reagenzhersteller und/oder von unabhangigen Laboratorien mit vom Hersteller unterstützten Reagenzien durchgeführt, dazu wurde eine reprasentative Stichprobe von Flaschchen dieser Produktcharge eingesetzt Die einzelnen Werte sollten im entsprechenden Akzeptanzbereich liegen, die tatsachlich erzielten Werte konnen jedoch wahrend der Lebensdauer dieser Kontrolle von den angegebenen Zielwerten abweichen. Abweichungen im Laufe der Zeit und zwischen verschiedenen Laboratorien sind möglicherweise auf unterschiedliche Labortechniken, Gerate und Reagenzien oder auf Modifikationen der Testmethoden durch den Hersteller zuruckzufuhren Jedem Labor wird empfohlen eigene Mittelwerte und Akzeptanzbereiche zu ermitteln und die hier aufgeführten Werte als Richtwerte zu betrachten

## SPEZIFISCHE EIGENSCHAFTEN

Dieses gefriergetrocknete Produkt wurde nach strengen Qualitätsstandards hergestellt. Um reproduzierbare Ergebnisse von Fläschchen zu Fläschchen sicherzustellen, muss die Kontrolle sachgerecht gelagert und wie angegeben gehandhabt werden.

FRANÇAIS

## UTILISATION

Lyphochek Tumor Marker Control est un sérum titré de contrôle de la qualité permettant de surveiller la précision des tests réalisés en laboratoire pour les analytes dont la liste figure sur cette notice

## INTRODUCTION ET PRINCIPE

L'utilisation de produits de contrôle de la qualité est indiquée pour évaluer de façon objective la précision des méthodes et des techniques utilisées, et fait partie intégrante des bonnes pratiques de laboratoire. Deux concentrations sont disponibles afin de permettre un contrôle de la qualité sur l'ensemble de la plage de valeurs cliniques

## RÉACTIF

Ce produit est préparé à partir de sérum humain auquel ont été ajoutés des constituants d'origine humaine et animale, des produits chimiques purs et des stabilisants Le contrôle est fourni sous forme lyophilisée pour assurer une meilleure stabilité

## CONSERVATION ET STABILITÉ

Ce produit restera stable jusqu'à la date de péremption en flacon non ouvert et conservé entre 2 et 8°C Une fois le contrôle reconstitué, tous les analytes resteront stables pendant 14 jours en flacon convenablement fermé et conservé entre 2 et 8°C Exceptions . La ferritine et le CA 27 29 seront stables pendant 6 jours. L'ACTH, le PSA libre, le PSA et la calcitonine doivent être titrés immédiatement après reconstitution Pour obtenir une précision optimale de la ferritine, laisser le flacon s'équilibrer pendant au moins 2 heures avant le titrage

Une fois le contrôle reconstitué et congelé, tous les analytes resteront stables pendant 30 jours en flacon convenablement fermé et conservé entre –10 et –20°C Une fois le contrôle décongelé, ne pas le recongeler et éliminer le produit restant

## RECONSTITUTION

A l'aide d'une pipette volumétrique, reconstituer chaque flacon avec 2,0 ml d'eau distillée ou désionisée Replacer le bouchon et laisser le produit reposer à température ambiante (entre 18 et 25°C) pendant environ 15 minutes, en l'agitant de temps en temps Avant utilisation, homogénéiser le produit en agitant plusieurs fois le flacon

## MODE OPÉRATOIRE

Ce produit doit être traité comme les échantillons de patients, en respectant les instructions accompagnant l'appareil, le kit ou le réactif utilisés

Tout déchet doit être éliminé conformément aux réglementations en vigueur dans le laboratoire pour le traitement des déchets Si le conditionnement est endommagé, contacter votre service technique Bio-Rad local

## LIMITES

1 Ne pas utiliser ce produit après la date de péremption

2. En cas de contamination microbienne ou de trouble excessif du contrôle reconstitué, éliminer le flacon

3 Ce produit n'est pas conçu pour être utilisé comme étalon

## DÉTERMINATION DES VALEURS

Les valeurs moyennes indiquées sur cette notice ont été déterminées a partir d'analyses répétées et concernent spécifiquement ce numéro de lot du produit. Les essais indiqués ont été réalisés par le fabricant du réactif et/ou par des laboratoires indépendants à l'aide de réactifs acceptés par le fabricant et sur un échantillonnage représentatif de ce lot de contrôle Les moyennes obtenues par un laboratoire donné doivent se trouver sur la plage de valeurs acceptables correspondante , cependant, les moyennes obtenues par le laboratoire peuvent varier par rapport aux valeurs indiquées pendant la durée de vie de ce contrôle Les variations dans le temps et entre laboratoires peuvent être dues à des différences de méthodes, d'appareils et de réactifs employés par chaque laboratoire ou à des modifications de la méthode d'analyse employée par le fabricant Il est recommandé à chaque laboratoire d'établir ses propres moyennes et plages de valeurs acceptables et de n'utiliser les valeurs fournies qu'à titre indicatif

## CARACTÉRISTIQUES

Ce produit lyophilisé est fabriqué selon des normes rigoureuses de contrôle de la qualité Pour obtenir des résultats reproductibles d'un flacon à l'autre, le contrôle doit être convenablement conservé et manipulé, tel que décrit dans cette notice

| IVD | CE | | | LOT | EXP | | EC REP | +2.0 mL $H_2O$ | REF |
|---|---|---|---|---|---|---|---|---|---|
| For In Vitro Diagnostic Use<br>In Vitro Diagnosticum<br>Usage In Vitro<br>Per Uso Diagnostico In Vitro<br>Para Uso Diagnóstico In Vitro<br>Utilizar Apenas Em Diagnóstico In Vitro<br>For in-vitro diagnostiskt bruk<br>Til in Vitro diagnosticering | European Conformity<br>CE-Konformitätskennzeichnung<br>Conformité aux normes européennes<br>Conformità europea<br>Conformidad europea<br>Conform dade com as normas europeias<br>Europeisk överensstämmelse<br>Europæisk overensstemmelse | Temperature Limit<br>Temperaturlimit<br>Limite de temperature<br>Limite di temperatura<br>Límite de temperatura<br>Limite de temperatura<br>Temperaturgränser<br>Temperaturgrænse | Consult Instructions for Use<br>Gebrauchsanweisung beachten<br>Consulter la notice d'emploi<br>Consultare le istruzioni per l'uso<br>Consulte las instrucciones de uso<br>Consulte as instruções de utilização<br>Las bruksanvisningen<br>Benyt brugsanvisninger | Lot Number<br>Charge Nr<br>Numero de lot<br>Numero di lotto<br>Numero de lote<br>Número de lote<br>Satsnummer<br>Batchnummer | Use by<br>Verwendbar bis<br>Date de péremption<br>Data di scadenza<br>Usar hasta el<br>Utilizar até<br>Använd före<br>Anvend før | Manufactured by<br>Hergestellt von<br>Fabriqué par<br>Fabricato da<br>Fabricado por<br>Fabricado por<br>Tillverkare<br>Fremstillet af | Authorized Representative<br>Bevollmächtigter<br>Représentant agréé<br>Rappresentante autorizzato<br>Representante autorizado<br>Representante autorizado<br>Auktoriserad representant<br>Autoriseret repræsentant | Reconstitute With<br>Rekonstituieren mit<br>A reconstituer avec<br>Ricostituito con<br>Reconstituir con<br>Reconstituir com<br>Spa ut med<br>Rekonstitueret med | Catalog Number<br>Katalognummer<br>Numéro de catalogue<br>Numero di catalogo<br>Numero de catálogo<br>Numero de catálogo<br>Katalognummer<br>Katalognr |

# Lyphochek® Tumor Marker Control Levels 1 and 2

## ITALIANO

### USO PREVISTO

Il Lyphochek Tumor Marker Control è un siero di controllo di qualità, dosato, formulato per monitorare la precisione delle procedure di analisi di laboratorio per gli analiti elencati nel presente inserto

### SOMMARIO E PRINCIPIO

L'uso di materiali per il controllo di qualità è indicato come valutazione oggettiva della precisione dei metodi e delle tecniche in uso, e costituisce parte integrante delle buone pratiche di laboratorio Per permettere di controllare le prestazioni nell'ambito di tutto l'intervallo clinico sono disponibili due livelli di controllo

### REATTIVO

Questo prodotto è stato preparato da siero umano con aggiunta di componenti di origine umana e animale, sostanze chimiche pure e stabilizzanti Questo controllo è fornito in forma liofila per aumentarne la stabilità

### CONSERVAZIONE E STABILITÀ

Questo prodotto è stabile fino alla data di scadenza quando viene conservato, non aperto, a 2-8°C Una volta ricostituito, tutti gli analiti sono stabili per 14 giorni quando il controllo è conservato ben chiuso a 2-8°C, con le seguenti eccezioni Ferritina e CA 27 29 sono stabili per 6 giorni ACTH, PSA Libero, PSA e Calcitonina vanno dosati immediatamente dopo la ricostituzione. Per ottenere una precisione ottimale della Ferritina, prima del dosaggio, lasciare che il controllo raggiunga l'equilibrio per almeno 2 ore

Dopo ricostituzione e congelamento, tutti gli analiti sono stabili per 30 giorni se il controllo è conservato ben chiuso a –10 / –20°C Non ricongelare il controllo una volta scongelato, gettare il materiale rimasto

### RICOSTITUZIONE

Con una pipetta volumetrica, ricostituire ogni flacone con 2,0 ml di acqua distillata o deionizzata Chiudere e lasciare riposare il controllo per circa 15 minuti a temperatura ambiente (18-25°C), agitando di tanto in tanto. Prima dell'uso, agitare delicatamente il flacone diverse volte per garantirne l'omogeneità

### PROCEDURA

Questo prodotto deve essere trattato allo stesso modo dei campioni in esame ed usato secondo le istruzioni che accompagnano lo strumento, il kit o il reattivo in uso

Eliminare eventuali materiali residui nel rispetto delle norme locali sullo smaltimento dei rifiuti Nel caso di danni alla confezione, contattare gli uffici Bio-Rad o l'agente di zona

### LIMITI

1 Questo prodotto non deve essere usato dopo la data di scadenza
2 In caso di evidente contaminazione microbica o di una eccessiva torbidezza nel controllo ricostituito, eliminare il flacone
3 Questo prodotto non è concepito per l'uso come standard di riferimento

### ASSEGNAZIONE DEI VALORI

I valori medi riportati in questo inserto sono il risultato di analisi in replicato e sono specifici per questo lotto di prodotto Le analisi sono state effettuate dai produttori dei reattivi e/o da laboratori indipendenti utilizzando reattivi forniti dal produttore ed una campionatura rappresentativa di questo lotto di controllo Le medie di ciascun laboratorio dovrebbero rientrare nel corrispondente intervallo di accettabilità, tuttavia i valori medi del laboratorio possono variare rispetto a quelli dichiarati per il periodo di validità del presente controllo Le variazioni nel tempo e tra laboratori possono essere causate da differenze nelle metodologie, strumentazioni o reattivi di ogni laboratorio o da modifiche metodologiche dei produttori dei reattivi Ogni laboratorio dovrebbe stabilire le proprie medie e i relativi intervalli di accettabilità ed utilizzare i valori pubblicati sull'inserto solo come guida

### CARATTERISTICHE

Questo è un prodotto liofilo stabilizzato preparato sotto un rigido controllo standard di qualità Per ottenere una consistente uniformità di risultati da flacone a flacone, si raccomanda una corretta conservazione e un corretto uso, come descritto

## ESPAÑOL

### USO INTENCIONADO

Lyphochek Tumor Marker Control tiene un uso intencionado como suero valorado para el control de la calidad y con el fin de supervisar la precisión de los procedimientos de análisis del laboratorio y para los analitos que se enumeran en este prospecto

### INTRODUCCIÓN Y PRINCIPIO

El uso de materiales para el control de la calidad está indicado para la evaluación objetiva de la precisión de los métodos y las técnicas en uso, y forma parte integral de las buenas prácticas del laboratorio Existen dos niveles de control para permitir supervisar el funcionamiento dentro del rango clínico

### REACTIVOS

Este producto está preparado a partir de suero humano al que se añaden constituyentes de origen humano y animal, sustancias químicas puras y estabilizadores El control se suministra liofilizado para aumentar su estabilidad

### CONSERVACIÓN Y ESTABILIDAD

Este producto permanecerá estable hasta la fecha de caducidad, siempre que esté almacenado sin abrir a una temperatura entre 2 y 8°C Una vez reconstituido el control, si se almacena bien tapado entre 2 y 8°C, todos los analitos permanecerán estables durante 14 días, con las siguientes excepciones Ferritina y CA 27 29 permanecerán estables durante 6 días. ACTH (hormona adrenocorticotrópica), PSA Libre, PSA y Calcitonina deben ser valorados inmediatamente después de la reconstitución Para lograr una precisión óptima con Ferritina, permita que el vial alcance el equilibrio durante al menos 2 horas antes del ensayo

Una vez reconstituido y congelado el control, siempre que se almacene bien tapado entre –10 y –20°C, todos los analitos permanecerán estables durante 30 días No vuelva a congelar el control una vez descongelado Deseche el material sobrante

### RECONSTITUCIÓN

Utilizando una pipeta graduada, reconstituya cada vial con 2,0 ml de agua destilada o desionizada Vuelva a taparlo y deje reposar el control a temperatura ambiente (entre 18 y 25°C) durante unos 15 minutos, girándolo en círculos de vez en cuando. Antes del muestreo, invierta el vial con suavidad para garantizar su homogeneidad

### PROCEDIMIENTO

Este producto debe tratarse de la misma forma que las muestras de pacientes y debe ser ensayado conforme a las instrucciones incluidas con el instrumento, kit o reactivos utilizados

Elimine todo material desechable de acuerdo con las normativas locales vigentes sobre la gestión de residuos En el caso de que el envoltorio haya sufrido daños, póngase en contacto con la oficina de ventas o con el Servicio técnico local de Bio-Rad

### LIMITACIONES

1 Este producto no debe utilizarse después de la fecha de caducidad
2. Si hubiese indicios de contaminación microbiana o exceso de turbidez en el producto reconstituido, deseche el vial
3 Este producto no está previsto para ser utilizado como estándar

### ASIGNACIÓN DE VALORES

Los valores medios que figuran en este prospecto se obtuvieron a partir de la replicación de análisis y son específicos de este lote del producto Las pruebas fueron realizadas por el fabricante del reactivo o por laboratorios independientes que utilizaron reactivos admitidos por el fabricante y una muestra representativa de este lote de control Las medias de cada laboratorio deben estar comprendidas en el correspondiente rango aceptable, pero pueden apartarse de los valores indicados mientras dure este control Las variaciones a lo largo del tiempo y entre laboratorios pueden deberse a diferencias en las técnicas del laboratorio, su instrumental y sus reactivos, o a modificaciones introducidas en el método de medida del fabricante Se recomienda que cada laboratorio establezca sus propias medias y rangos aceptables y utilicen los que aquí se proporcionan sólo como orientación

### CARACTERÍSTICAS ESPECÍFICAS DE FUNCIONAMIENTO

## PORTUGUES

### UTILIZAÇÃO

O Lyphochek Tumor Marker Control destina-se a ser utilizado como soro de controlo da qualidade ensaiado para controlar a precisão dos procedimentos laboratoriais de análise para os analitos listados neste folheto informativo

### SUMÁRIO E PRINCÍPIO

A utilização de materiais de controlo da qualidade é indicada como uma avaliação objectiva da precisão de métodos e técnicas aplicados e é parte integrante das boas práticas laboratoriais Encontram-se disponíveis dois níveis de controlo para permitir afenr o desempenho dentro dos limites clínicos

### REAGENTE

Este produto é preparado a partir de soro humano acrescido de constituintes de origem humana e animal, substâncias químicas puras e estabilizadores O controlo é fornecido sob forma liofilizada para maior estabilidade

### ARMAZENAMENTO E ESTABILIDADE

Este produto permanecerá estável até ao fim do prazo de validade desde que seja armazenado por abrir a uma temperatura de 2 a 8°C Depois de o controlo ter sido reconstituído, todos os analitos permanecerão estáveis durante 14 dias desde que o produto seja armazenado com a tampa firmemente apertada a uma temperatura de 2 a 8°C, com as seguintes excepções a Ferritina e o CA 27 29 permanecerão estáveis durante 6 dias. A ACTH, o PSA Livre, o PSA e a Calcitonina devem ser ensaiados imediatamente após a reconstituição. Para obter a melhor precisão em relação à Ferritina, deixe o frasco repousar para atingir um equilíbrio durante um mínimo de 2 horas antes do ensaio

Depois de reconstituído e congelado o controlo, todos os analitos permanecerão estáveis durante 30 dias quando o controlo é armazenado com a tampa firmemente apertada a uma temperatura de –10 a –20°C Depois de o controlo ter sido descongelado, não deve voltar a ser congelado, elimine qualquer material restante

### RECONSTITUIÇÃO

Utilizando uma pipeta volumétrica, reconstitua cada frasco com 2,0 mL de água destilada ou desionizada Reponha a tampa e deixe o controlo repousar à temperatura ambiente (18 a 25°C) durante cerca de 15 minutos, agitando o frasco de vez em quando Antes de efectuar a recolha da amostra, inverta suavemente o frasco vánas vezes para assegurar a homogeneidade

### PROCEDIMENTO

Este produto deve ser tratado da mesma forma que as amostras de pacientes e utilizado de acordo com as instruções que acompanham o instrumento, dispositivo ou reagente que está a ser utilizado

Elimine todos os materiais descartados de acordo com as disposições locais em vigor para a eliminação de resíduos biológicos Na eventualidade de observar danos na embalagem, contacte a Bio-Rad Laboratories.

### LIMITAÇÕES

1 Este produto não deve ser utilizado após o fim do prazo de validade
2 Se existir evidência de contaminação microbiana ou turvação excessiva no controlo reconstituído, elimine o frasco
3. Este produto não deve ser utilizado como um calibrador

### VALORIZAÇÕES

Os valores médios impressos neste folheto derivam de análises repetidas e são específicos para este lote do produto Os testes listados foram executados pelo fabricante do reagente e/ou por laboratórios independentes que utilizam os reagentes de acordo com as especificações do fabricante e uma amostra significativa deste lote de controlo As médias laboratoriais individuais devem estar dentro dos limites correspondentes aceitáveis, no entanto, as médias laboratoriais podem variar dos valores listados durante o tempo de duração deste controlo. Variações ao longo do tempo e entre laboratórios podem dever-se a diferenças de tecnicas, instrumentos ou reagentes, ou a modificações nas técnicas de teste pelo fabricante Recomenda-se que cada laboratorio estabeleça as suas próprias medias e limites aceitáveis e utilize as que são fornecidas apenas como guias

### CARACTERÍSTICAS ESPECÍFICAS DE DESEMPENHO

Este produto é liofilizado e fabricado de acordo com os mais rígidos padrões de controlo da qualidade Para obter valorizações consistentes de frasco para frasco, o controlo deve ser manuseado e armazenado de acordo com o descrito

## SVENSKA

### AVSEDD ANVÄNDNING

Lyphochek Tumor Marker Control ar ett analyserat kvalitetskontrollserum avsett for kontroll av precisionen i testforfaranden på laboratorium for de analyter som anges i denna bipacksedel

### SAMMANFATTNING OCH PRINCIP

Anvandning av kvalitetskontrollmaterial ar indicerad for objektiv utvardering av precisionen i anvanda metoder och tekniker och ingår i god laboratoriepraxis. Två kontrollnivåer finns tillgangliga för kontroll av prestandan inom det kliniska mätområdet

### REAGENS

Denna produkt ar framstàlld av humant serum med tillsatser av humant och animaliskt ursprung, rena kemikalier och stabiliseringsmedel Kontrollen tillhandahålles i frystorkad form for okad hållbarhet

### FÖRVARING OCH HÅLLBARHET

Denna produkt ar hållbar fram till utgångsdatum vid forvaring i oopppnad forpackning vid 2-8°C Efter att kontrollen har rekonstituerats och vid forvaring i tatt forsluten flaska vid 2-8°C ar alla analyter hållbara i 14 dagar, med foljande undantag Ferritin och CA 27 29 är endast hållbara i 6 dagar ACTH fritt PSA, PSA och kalcitonin skall analyseras omedelbart efter rekonstituering För optimal precision för ferritin bor flaskan stå och ekvilibreras minst 2 timmar fore analys

Efter att kontrollen har rekonstituerats och frusits och vid forvaring i tatt forsluten flaska vid –10 till –20°C ar alla analyter hållbara i 30 dagar. Efter upptining får kontrollen ej återfrysas utan resterande material skall kasseras

### REKONSTITUERING

Anvand en volumetrisk pipett och rekonstituera varje flaska med 2,0 mL destillerat eller avjoniserat vatten Satt på proppen igen och låt kontrollen stå i rumstemperatur (18 till 25°C) i ca 15 minuter, och snurra den då och då for hand Vand flaskan upp och ner forsiktigt flera gånger så att innehållet blandas ordentligt fore anvandning

### FÖRFARANDE

Denna produkt skall behandlas på samma satt som patientprover och anvandas enligt anvisningarna for de instrument, kit och reagenser som används

Kasserat material skall bortskaffas enligt de avfallsbestammelser som utfardats av lokala myndigheter. Om förpackningen ar skadad kontaktas narmaste Bio-Rad Laboratories forsaljningsavdelning eller teknisk serviceavdelning

### BEGRÄNSNINGAR

1 Denna produkt skall inte anvandas efter utgångsdatum
2 Vid tecken på mikrobiell kontaminering eller om den rekonstituerade kontrollen ar mycket grumlig skall flaskan kasseras
3 Denna produkt är inte avsedd att användas som en standard

### TILLDELNING AV VARDEN

Medelvardena som anges i denna bipacksedel ar harledda via replikatanalyser och ar specifika for denna kontrollbatch De angivna testerna har utförts av reagenstillverkaren och/eller på oberoende laboratorier med anvandning av tillverkarens reagenser och ett representativt prov från denna kontrollbatch Medelvardena på det enskilda laboratoriet bor ligga inom motsvarande acceptabla område, laboratoriets medelvarden kan dock skilja sig från de angivna vardena under kontrollens livstid Variationer over tiden och från laboratorium till laboratorium kan bero på skillnader i laboratorieteknik, instrument och reagenser, eller på modifikationer i tillverkarens testmetoder Det rekommenderas att varje laboratorium faststaller sina egna medelvärden och acceptabla områden och endast betraktar de hari angivna vardena som vagledande.

### SPECIFIKA PRODUKTEGENSKAPER

Denna produkt ar en frystorkad produkt som framstalls enligt strikta kvalitetskontrollstandarder För jamna analysresultat från flaska till flaska skall kontrollen forvaras och hanteras korrekt enligt anvisningarna

# Lyphochek® Tumor Marker Control Levels 1 and 2

DANSK

**TILSIGTET ANVENDELSE**

Lyphochek Tumor Marker Control er beregnet til anvendelse som en analyseret kvalitetskontrolserum med henblik på overvågning af præcisionen af laboratoriets analysemetoder for de analytter, der er angivet i indlægssedlen

**RESUMÉ OG PRINCIP**

Anvendelsen af kvalitetskontrolmateriale er tilsigtet som en objektiv vurdering af de anvendte metoders og teknikkers præcision og er en integreret del af god laboratoriepraksis Der findes to kontrolniveauer tilgængelige til overvågning af præstationen inden for det kliniske område

**REAGENS**

Dette produkt er fremstillet af human serum tilsat bestanddele af human og animalsk oprindelse og rene kemikalier og stabilisatorer. Denne kontrol leveres i frysetørret form for at forøge stabiliteten

**OPBEVARING OG STABILITET**

Dette produkt er holdbart indtil udløbsdatoen ved opbevaring uåbnet ved 2-8°C. Efter rekonstituering vil alle analytter være holdbare i 14 dage ved opbevaring med tæt lukket låg ved 2-8°C, med følgende undtagelser: Ferritin og CA 27.29 vil være holdbare i 6 dage ACTH, frit PSA, PSA og calcitonin bør analyseres umiddelbart efter rekonstituering For optimal præcision af ferritin bør ampullen ekvilibrere i mindst 2 timer inden analysering

Efter rekonstituering og frysning af kontrollen vil alle analytter være holdbare i 30 dage ved opbevaring med tæt lukket låg ved −10 til −20°C Optøet kontrolmateriale må ikke fryses igen, resten af materialet kasseres

**REKONSTITUERING**

Hver ampul rekonstitueres ved hjælp af en automatpipette med 2,0 ml destilleret eller deioniseret vand Sæt omgående låget på igen, og lad kontrolmaterialet stå i stuetemperatur (18-25°C) i ca. 15 minutter, idet det blandes fra tid til anden Inden analysering vendes ampullen forsigtigt flere gange for at sikre homogenitet.

**FREMGANGSMÅDE**

Dette produkt skal behandles som patientprøver og anvendes iht. de vejledninger, der følger med det anvendte instrument, reagenskit eller reagens.

Kasseret materiale skal bortskaffes iht gældende affaldsregulativer Hvis emballagen er beskadiget, kontaktes den lokale Bio-Rad Laboratories forhandler eller teknisk service hos Bio-Rad Laboratories

**BEGRÆNSNINGER**

1 Dette produkt bør ikke anvendes efter udløbsdatoen
2 Hvis der er tegn på mikrobiel kontaminering i det rekonstituerede kontrolmateriale, eller det er meget uklart, skal ampullen kasseres
3 Dette produkt er ikke beregnet til anvendelse som standard

**FASTSÆTTELSE AF VÆRDIER**

De middelværdier, der er trykt i denne indlægssedel, er udledt af gentagne analyser og er specifikke for dette produktlot De angivne analyser er udført af reagensproducenten og/eller uafhængige laboratorier vha producentens reagenser og et repræsentativt udvalg af dette lot af kontrolmateriale Individuelle laboratoriemiddelværdier bør ligge inden for det i indlægssedlen angivne referenceområde, men kan dog variere i forhold til de angivne værdier i løbet af kontrolmaterialets levetid. Variationer over tid og imellem laboratorier kan skyldes forskellige laboratorieteknikker, instrumenter og reagenser, eller modifikationer i testmetoder fra producentens side Det anbefales at laboratorier etablerer deres egne middelværdier og referenceområder og kun betragter de medfølgende værdier som vejledende

**SPECIFIKKE YDELSESEGENSKABER**

Dette produkt er et frysetørret produkt, der er produceret under strenge kvalitetskontrolkrav Kontrolmaterialet skal opbevares korrekt og håndteres som anvist for at give pålidelige resultater

**日本語**

**序論**

Lyphochek Tumor Marker Control （ライフォチェック腫瘍マーカーコントロール）は、本インサートに記載されている検査成分を対象とした臨床検査における精度管理のためのコントロール血清です 。

**概要と意義**

測定法や測定技術の精度を客観的に評価するために精度管理物質が使用されます。精度管理物質は、検査室の臨床試験に必須の管理手法の一部です。臨床的に有意義な2濃度のコントロール血清から構成されています。

**試薬**

本製品はヒト血清をベースとして、ヒトおよび動物由来成分、純粋な化学物質、および安定剤を添加して調整されています。また、長期の安定性を得るために凍結乾燥品となっています。

**貯法および安定性**

未開封のまま2～8℃で保存した場合、有効期限まで安定です。溶解後密栓し2～8℃で保存した場合、次の成分を除いては、全成分14日間安定です。フェリチンおよびCA 27.29は6日間安定です。ACTH、遊離PSA、PSA、およびカルシトニンは、溶解直後にご使用ください。使用前に、本製品を少なくとも2時間平衡化して、フェリチンの精度を最適化してください 。

溶解後凍結し、密栓して-10～-20℃で保存した場合、30日間安定です。融解後は再凍結せず、残った本製品は廃棄してください。

**溶解法**

ホールピペットを用いて、2 0mLの蒸留水または脱イオン水を加えて溶解してください。密栓し、時々旋回混和しながら室温（18～25℃）で約15分間放置してください。使用前に、溶液が均一になるようにバイアルを数回緩やかに転倒混和してください。

**使用方法**

本製品は、患者検体と同様に取り扱い、使用する測定機器やキット、試薬などの指示に従ってご使用ください 。

廃棄する場合は、国や各自治体の指示に従って廃棄してください。パッケージに損傷のある場合は、お近くのバイオ・ラッド　ラボラトリーズ社の営業所またはテクニカルサービス部門へご連絡ください。

**使用上の注意**

（1） 有効期限の過ぎた本製品は、ご使用にならないでください。

（2） 溶解後微生物の混入や顕著な混濁が認められた場合は、バイアルを廃棄してください。

（3） 本製品を標準物質として使用しないでください。

**表示値**

本インサートに記載されている平均値は、複数の検査データより得られたもので、本ロット特有の値です。記載されている値は、試薬メーカーまたは外部の検査施設により、試薬メーカーの試薬とこのロットの代表サンプルを用いて得られた測定値です。検査施設で求められた平均値は、表示値に記載された許容範囲内に収まるはずですが、本製品の有効期間中でも範囲外になる場合があります。表示値には測定方法、測定技術、機器および試薬間の変動が含まれています。測定成績は、それぞれの機器、試薬の状態に基づくため、各施設で独自の平均値と許容範囲を設定し、本インサートに記載した数値は参考値としてご使用になることをお勧めします。

**性能特性**

本製品は、厳しい品質管理基準に従って製造された凍結乾燥品です。バイアル間での測定値の変動を防ぐために、前述したように適切に保存し取り扱ってください。

**精度管理用**

**脚注**

（1） 記載された値が高値スタンダードの濃度値を超える場合には、試験前に本製品を希釈してください。

（2） 試験キット/機器は、FDAの認定を受けていません。各成分の試薬の規制に関する情報は、21 § CFR 809.30を参照してください。

（3） CA 15-3、CA 72-4、CA 19-9、およびCA 125は、Fujirebio, Inc （200 Great Valley Parkway, Malvern, PA 19355）の1部門であるFujirebio Diagnosticsの商標です。

（4） CYFRA 21-1 RIAは、KS 19 1およびBM 19.21抗体システム（Fujirebio, Inc ならびにその代理店およびライセンシーがRoche GmbHよりライセンスを受けている）に基づいています。

（5） 非スパイク成分の性能や安定性に関しては、データがありません。

## WARNING // Warnung // Attention // Avvertenze // Precaución // Aviso // Varning // Advarsel

ENGLISH

**Biological source material. Treat as potentially infectious.**

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2 This product may also contain other human source material for which there are no approved tests In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens

DEUTSCH

**Material biologischer Herkunft. Als potentiell infektiös zu behandeln.**

Jede zur Herstellung dieser Kontrolle verwendete menschliche Spendereinheit wurde mit von der amerikanischen Arzneimittelbehörde FDA (Food and Drug Administration) zugelassenen Methoden getestet und als nicht-reaktiv bezüglich Hepatitis-B-Oberflachen-Antigen (HBsAg), Antikörper gegen Hepatitis C (HCV) und Antikörper gegen HIV-1/HIV-2 befunden. Das Produkt enthalt moglicherweise auch andere Bestandteile menschlichen Ursprungs, fur die keine zugelassenen Tests existieren. In Übereinstimmung mit der guten Laborpraxis sollten alle Materialien menschlichen Ursprungs als potentiell infektiös betrachtet und mit der gleichen Sorgfalt wie Patientenproben behandelt werden

FRANÇAIS

**Produit d'origine biologique. A considérer comme potentiellement infectieux.**

Chaque unité de produit provenant d'un donneur humain et utiliséeutilisé dans la préparation de ce contrôle a été analysée à l'aide de méthodes approuvées par la FDA et a présenté des résultats négatifs pour l'antigène de surface de l'hépatite B (AgHBs), et les anticorps de l'hépatite C (VHC) et du VIH-1/VIH-2. Il est possible que ce produit contienne d'autres substances d'origine humaine pour lesquelles il n'existe pas de test agréé Conformément aux bonnes pratiques de laboratoire, toute substance d'origine humaine doit être considérée comme potentiellement infectieuse et manipulée avec les mêmes précautions que les échantillons provenant de patients.

ITALIANO

**Materiale di origine biologica. Trattare come potenzialmente infettivo.**

Ciascuna unità donatore utilizzata per preparare questo controllo è stata testata mediante metodi approvati dalla FDA e risultata non reattiva per l'antigene di superficie dell'epatite B (HBsAg), l'anticorpo contro l'epatite C (HCV) e l'anticorpo contro l'HIV-1/HIV-2 Questo prodotto può anche contenere altro materiale di origine umana per il quale non esistono procedure di dosaggio raccomandate Secondo le buone pratiche di laboratorio, tutti i materiali di origine umana devono essere considerati potenzialmente infettivi, perciò si raccomanda di trattare questo prodotto con le medesime precauzioni adottate per i campioni dei pazienti.

ESPAÑOL

**Material de origen biológico. Manipular como potencialmente infeccioso.**

Todas las unidades de donantes humanos utilizadas en la fabricación de este control se han analizado según métodos de análisis aceptados por la FDA (agencia estadounidense para alimentos y fármacos) y se ha determinado que no reaccionan contra el antígeno superficial de la hepatitis B (HBsAg), el anticuerpo de la hepatitis C (VHC) y el anticuerpo del VIH-1/VIH-2 Este producto puede contener asimismo material de origen humano para el que no existen análisis homologados De acuerdo con las prácticas de laboratorio correctas, todo material de origen humano se debe considerar potencialmente infeccioso y manipular con las mismas precauciones que las muestras de pacientes

PORTUGUÊS

**Material de origem biológica. Tratar como potencialmente infeccioso.**

Cada dádiva humana utilizada no fabrico deste controlo foi testada pelos métodos aprovados pela FDA (Administração dos Alimentos e Fármacos dos Estados Unidos), tendo sido considerada não reactiva em antigénios de superfície da hepatite B (HBsAg), anticorpo da hepatite C (VHC) e anticorpos HIV-1/HIV-2. Este produto também poderá conter outros materiais de origem humana para os quais não existem testes aprovados De acordo com as boas práticas laboratoriais, todo o material de origem humana deve ser considerado potencialmente infeccioso, pelo que deverá ser manuseado com as mesmas precauções utilizadas com as amostras dos pacientes

SVENSKA

**Material av biologiskt ursprung. Skall behandlas som potentiellt infektiöst.**

Varje enhet från humana donatorer till denna kontroll har testats enligt FDA-godkända metoder och har visat sig icke-reaktiv for hepatit B ytantigen (HBsAg), antikroppar mot hepatit C (HCV)och antikroppar mot HIV-1/HIV-2 Denna produkt kan aven innehålla annat material av humant ursprung, for vilket godkanda tester saknas Enligt god laboratoriepraxis bor alla material av humant ursprung betraktas som potentiellt infektiosa och hanteras enligt samma forsiktighetsregler som patientprover

DANSK

**Biologisk kildemateriale. Bør behandles som potentiel smittekilde.**

Hver human donorenhed, der er anvendt ved fremstilling af dette produkt, er blevet testet med metoder, der er godkendte af FDA, og er fundet ikke-reaktiv over for hepatitis B overfladeantigen (HBsAg), antistof mod hepatitis C (HCV) og antistof mod HIV-1/HIV-2. Dette produkt kan også indeholde andet humant kildemateriale, for hvilket der ikke findes godkendte tests. I overensstemmelse med god laboratoriepraksis bør alle materialer af human oprindelse betragtes som potentiel smittekilde og håndteres efter samme forholdsregler som patientprøver

日本語

**感染注意**
**本製品はヒト由来成分を含んでいます。ご使用の際は、感染の可能性があるものとして、検体と同様に十分注意してお取り扱いください。**

原料血液は、HBs抗原、HCV抗体、およびHIV-1/2抗体検査を米国FDA認定試薬を用いて供血者ごとに行い、陰性の結果を得ています。しかし、現在ヒト血液に由来する製剤の感染性を完全に否定する測定法は確立されておりません。したがって、本製品をご使用の際は、医薬品の臨床試験基準に従い、すべてのヒト由来物質に感染の可能性があるものとして、十分注意して取り扱ってください。

| GLOSSARY | GLOSSAR | GLOSSAIRE | GLOSSARIO | GLOSARIO | GLOSSÁRIO | ORDLISTA | ORDLISTE |
|---|---|---|---|---|---|---|---|
| ANALYTES | ANALYTE | ANALYTES | ANALITI | ANALITOS | ANALITOS | ANALYTER | ANALYTTER |
| ACTH | ACTH | ACTH | ACTH | ACTH | ACTH | ACTH | ACTH |
| AFP | AFP | AFP | AFP | AFP | AFP | AFP | AFP |
| Aldosterone | Aldosteron | Aldosterone | Aldosterone | Aldosterona | Aldosterona | Aldosteron | Aldosteron |
| Beta-2-Microglobulin | Beta-2-Mikroglobulin | Bêta-2-microglobuline | Beta-2-microglobulina | Beta-2-Microglobulina | Beta-2-microglobulina | Beta-2-mikroglobulin | Beta-2-microglobulin |
| CA 15-3 | GA 15-3 | CA 15-3 | CA 15-3 | CA 15-3 | CA 15-3 | CA 15-3 | CA 15-3 |
| CA 19-9 | CA 19-9 | CA 19-9 | CA 19-9 | CA 19-9 | CA 19-9 | CA 19-9 | CA 19-9 |
| CA 27 29 | CA 27 29 | CA 27 29 | CA 27 29 | CA 27 29 | CA 27 29 | CA 27 29 | CA 27 29 |
| CA 50 | CA 50 | CA 50 | CA 50 | CA 50 | CA 50 | CA 50 | CA 50 |
| CA 72-4 | CA 72-4 | CA 72-4 | CA 72-4 | CA 72-4 | CA 72-4 | CA 72-4 | CA 72-4 |
| CA 125 | CA 125 | CA 125 | CA 125 | CA 125 | CA 125 | CA 125 | CA 125 |
| CA 195 | CA 195 | CA 195 | CA 195 | CA 195 | CA 195 | CA 195 | CA 195 |
| CA 549 | CA 549 | CA 549 | CA 549 | CA 549 | CA 549 | CA 549 | CA 549 |
| Calcitonin | Calcitonin | Calcitonine | Calcitonina | Calcitonina | Calcitonina | Kalcitonin | Calcitonin |
| CASA | CASA | CASA | CASA | CASA | CASA | CASA | CASA |
| CEA | CEA | CEA | CEA | CEA | CEA | CEA | CEA |
| CYFRA 21-1 | CYFRA 21-1 | CYFRA 21-1 | CYFRA 21-1 | CYFRA 21-1 | CYFRA 21-1 | CYFRA 21-1 | CYFRA 21-1 |
| Ferritin | Ferritin | Ferritine | Ferritina | Ferritina | Ferritina | Ferritin | Ferritin |
| hCG (Human Chorionic Gonadotropin) | hCG (Humanes Choriongonadotropin) | hCG (Gonadotrophine chorionique humaine) | hCG (Gonadotropina corionica umana) | hCG (Gonadotropina coriónica humana) | hCG (Gonadotropina coriónica humana) | HCG (humant koriongonadotropin) | hCG (humant chorongonadotropin) |
| hCG – Beta Subunit | hCG-Beta-Untereinheit | Sous-unité hCG-bêta | Sottounità hCG-Beta | hCG - Subunidad Beta | Subunidade beta hCG | HCG-beta-subenhet | hCG-beta subunit |
| Interleukin-2 Receptor (5) | Interleukin-2-Rezeptor (5) | Récepteur de l'interleukine 2 (5) | Recettore dell'interleukina 2 (5) | Receptor de interleucina-2 (5) | Receptor de interleucina-2 (5) | Interleukin-2-receptor (5) | Interleukin-2 receptor (5) |
| NSE (Neuron Specific Enolase) | NSE (Neuronenspezifische Enolase) | NSE (énolase neurospecifique) | NSE (enolasi neurone specifica) | NSE (Enolasa especifica neuronal) | NSE (Enolase neuro-especifica) | NSE (neuronspecifikt enolas) | NSE (neuronspecifik enolase) |
| OV2 (5) | OV2 (5) | OV2 (5) | OV2 (5) | OV2 (5) | OV2 (5) | OV2 (5) | OV2 (5) |
| PAP (Prostatic Acid Phosphatase) | PAP (Prostataspezifische saure Phosphatase) | PAP (phosphatase acide prostatique) | PAP (Fosfatasi acida prostatica) | Fosfatasa Acida Prostática (PAP) | PAP (Fosfatase ácida prostática) | PAP (prostataspecifikt surt fosfatas) | PAP (prostataspecifik sur phosphatase) |
| Prolactin | Prolactin | Prolactine | Prolattina | Prolactina | Prolactina | Prolaktin | Prolactin |
| PSA (Prostate Specific Antigen) | PSA (Prostataspezifisches Antigen) | PSA (antigène prostatique specifique) | PSA (Antigene specifico della prostata) | Antigeno prostático especifico (PSA) | PSA (Antigenio especifico da próstata) | PSA (prostataspecifikt antigen) | PSA (prostataspecifikt antigen) |
| Free PSA | Freies PSA | PSA, libre | PSA libero | PSA Libre | PSA Livre | PSA, fritt | Fnt PSA |
| TPA (Tissue Polypeptide Antigen) (5) | TPA (Gewebe-Polypeptid-Antigen) (5) | TPA (antigène polypeptidique tissulaire) (5) | TPA (Antigene polipeptide tissutale) (5) | TPA (Antígeno polipeptídico tisular) (5) | TPA (Antigénio policeptidico teadual) (5) | TPA (Tissue polypeptid antigen (vavnadsmarkör)) (5) | TPA (vævspolypeptid antigen) (5) |
| TERMS | BEZEICHNUNG | TERMES | TERMINOLOGIA | TÉRMINOS | REACÇÕES | VILLKOR | GRÆNSER |
| Mean | Mittelwert | Moyenne | Media | Media | Média | Medelvarde | Gennemsnit |
| Range | Bereich | Plage de valeurs | Intervallo | Rango | Limites | Område | Område |
| Units | Einheiten | Unités | Unita | Unidades | Unidades | Enheter | Enheder |

| | UNITS | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE | SI | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE |
|---|---|---|---|---|---|---|---|---|---|---|
| **ACTH (ADRENOCORTICOTROPIC HORMONE)** | | | | | | | | | | |
| Diagnostic Products Immulite | pg/mL | 92 | 63 – 121 | 392 | 312 – 472 | pmol/L | 20.2 | 13.9 – 26.6 | 86 | 69 – 104 |
| Diagnostic Products Immulite 2000 | pg/mL | 111 | 83 – 140 | 426 | 329 – 524 | pmol/L | 24.4 | 18.3 – 30.8 | 94 | 72 – 115 |
| DiaSorin RIA | pg/mL | 36 | 22 – 51 | 235 | 153 – 317 | pmol/L | 8.0 | 4.8 – 11.2 | 52 | 34 – 70 |
| DiaSorin IRMA | pg/mL | 101 | 75 – 127 | 341 | 266 – 416 | pmol/L | 22.2 | 16.5 – 27.9 | 75 | 59 – 92 |
| **AFP (ALPHA-FETOPROTEIN)** | | | | | | | | | | |
| Abbott Architect | ng/mL | 28 | 23 – 34 | 120 | 96 – 145 | µg/L | 28 | 23 – 34 | 120 | 96 – 145 |
| Abbott AxSYM | ng/mL | 24 | 19 – 29 | 115 | 92 – 138 | µg/L | 24 | 19 – 29 | 115 | 92 – 138 |
| Abbott IMx | ng/mL | 20 | 16 – 23 | 103 | 83 – 124 | µg/L | 20 | 16 – 23 | 103 | 83 – 124 |
| Adaltis BRIDGE (2) | IU/mL | 24 | 19 – 29 | 118 | 67 – 168 | kIU/L | 24 | 19 – 29 | 118 | 67 – 168 |
| Adaltis SR1 (Automated System) (2) | IU/mL | 21 | 16 – 26 | 88 | 59 – 117 | kIU/L | 21 | 16 – 26 | 88 | 59 – 117 |
| Bayer ACS.180 | ng/mL | 28 | 22 – 33 | 110 | 88 – 132 | µg/L | 28 | 22 – 33 | 110 | 88 – 132 |
| Bayer Advia Centaur | ng/mL | 27 | 21 – 32 | 110 | 88 – 132 | µg/L | 27 | 21 – 32 | 110 | 88 – 132 |
| Bayer Immuno I | ng/mL | 23 | 18 – 28 | 91 | 73 – 109 | µg/L | 23 | 18 – 28 | 91 | 73 – 109 |
| Beckman Coulter ACCESS (WHO 1st IS 72/225) | ng/mL | 25 | 21 – 29 | 107 | 90 – 124 | µg/L | 25 | 21 – 29 | 107 | 90 – 124 |
| BioCheck EIA (WHO 1st IS 72/225) (2) | ng/mL | 20 | 13 – 27 | 91 | 59 – 123 | µg/L | 20 | 13 – 27 | 91 | 59 – 123 |
| bioMérieux VIDAS (2) | IU/mL | 20 | 14 – 26 | 90 | 67 – 113 | kIU/L | 20 | 14 – 26 | 90 | 67 – 113 |
| Byk-Sangtec IRMA RIA-mat 280 (1st IS 72/225) (2) | IU/mL | 21 | 16 – 25 | 91 | 78 – 104 | kIU/L | 21 | 16 – 25 | 91 | 78 – 104 |
| Byk-Sangtec LIA-mat S300 (1st IS 72/225) (2) | IU/mL | 21 | 15 – 28 | 92 | 68 – 115 | kIU/L | 21 | 15 – 28 | 92 | 68 – 115 |
| Byk-Sangtec LIAISON (1st IS 72/225) (2) | IU/mL | 20 | 17 – 23 | 86 | 76 – 96 | kIU/L | 20 | 17 – 23 | 86 | 76 – 96 |
| CanAg EIA (2) | ng/mL | 26 | 22 – 30 | 118 | 100 – 136 | µg/L | 26 | 22 – 30 | 118 | 100 – 136 |
| CIS RIA gnost (WHO 72/225) | IU/mL | Δ | | Δ | | kIU/L | Δ | | Δ | |
| Diagnostic Products Coat-A-Count IRMA (2) | IU/mL | 20 | 16 – 23 | 84 | 70 – 98 | kIU/L | 20 | 16 – 23 | 84 | 70 – 98 |
| Diagnostic Products Immulite | IU/mL | 18 | 16 – 20 | 78 | 69 – 87 | kIU/L | 18 | 16 – 20 | 78 | 69 – 87 |
| Diagnostic Products Immulite 2000 | IU/mL | 18 | 16 – 19 | 79 | 72 – 85 | kIU/L | 18 | 16 – 19 | 79 | 72 – 85 |
| Diagnostic Products TC Double Antibody IRMA | IU/mL | 17 | 12 – 22 | 94 | 75 – 112 | kIU/L | 17 | 12 – 22 | 94 | 75 – 112 |
| DiaSorin M-K-S (WHO 72/225) (2) | ng/mL | 23 | 16 – 30 | 98 | 74 – 123 | µg/L | 23 | 16 – 30 | 98 | 74 – 123 |
| Immunotech IRMA (WHO 72/225) (2) | IU/mL | 22 | 18 – 27 | 99 | 79 – 119 | kIU/L | 22 | 18 – 27 | 99 | 79 – 119 |
| Ortho Clinical Diagnostic Vitros ECi (1st IRP 72/225) | IU/mL | 19 | 15 – 22 | 75 | 60 – 89 | kIU/L | 19 | 15 – 22 | 75 | 60 – 89 |
| Radim BRIO (WHO 72/225) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Radim IRMA CT (WHO 72/225) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Roche Cobas Core EIA (2) | IU/mL | 23 | 17 – 28 | 103 | 81 – 124 | kIU/L | 23 | 17 – 28 | 103 | 81 – 124 |
| Roche Elecsys | IU/mL | 20 | 14 – 26 | 90 | 63 – 117 | kIU/L | 20 | 14 – 26 | 90 | 63 – 117 |
| TOSOH AIA-PACK IEMA (IS 72/225) | ng/mL | 24 | 19 – 28 | 108 | 92 – 124 | µg/L | 24 | 19 – 28 | 108 | 92 – 124 |
| UBI Magiwel Quantitative (WHO 72/225) (2) | IU/mL | 20 | 16 – 24 | 70 | 55 – 84 | kIU/L | 20 | 16 – 24 | 70 | 55 – 84 |
| **ALDOSTERONE** | | | | | | | | | | |
| Diagnostic Products Coat-A-Count | pg/mL | 215 | 170 – 260 | 1145 | 1005 – >1200 | pmol/L | 596 | 471 – 720 | 3172 | 2784 – >3324 |
| DiaSorin ALDOCTK-2 (2) | pg/mL | 248 | 173 – 322 | >1000 | | pmol/L | 687 | 480 – 892 | >2770 | |
| **BETA-2-MICROGLOBULIN** | | | | | | | | | | |
| Abbott IMx | µg/mL | 1.1 | 0.9 – 1.3 | 3.7 | 3.0 – 4.5 | mg/L | 1.1 | 0.9 – 1.3 | 3.7 | 3.0 – 4.5 |
| Bayer Immuno 1 | µg/mL | 1.1 | 0.9 – 1.3 | 3.6 | 2.9 – 4.3 | mg/L | 1.1 | 0.9 – 1.3 | 3.6 | 2.9 – 4.3 |
| BioCheck EIA | µg/mL | 1.0 | 0.8 – 1.2 | 4.0 | 2.6 – 5.4 | mg/L | 1.0 | 0.8 – 1.2 | 4.0 | 2.6 – 5.4 |
| bioMérieux VIDAS (2) | µg/mL | Δ | | Δ | | mg/L | Δ | | Δ | |
| Byk-Sangtec LIAISON (2) | µg/mL | 1.1 | 0.8 – 1.4 | 3.8 | 3.2 – 4.4 | mg/L | 1.1 | 0.8 – 1.4 | 3.8 | 3.2 – 4.4 |
| Diagnostic Products Coat-A-Count IRMA | µg/mL | Δ | | Δ | | mg/L | Δ | | Δ | |
| Diagnostic Products Immulite | µg/mL | 3.0 | 2.5 – 3.4 | 7.9 | 6.4 – 9.3 | mg/L | 3.0 | 2.5 – 3.4 | 7.9 | 6.4 – 9.3 |
| Diagnostic Products Immulite 2000 | µg/mL | 1.5 | 1.3 – 1.6 | 4.1 | 3.7 – 4.5 | mg/L | 1.5 | 1.3 – 1.6 | 4.1 | 3.7 – 4.5 |
| Immunotech RIA (WHO 1st IS 185) (2) | µg/mL | 1.3 | 1.0 – 1.6 | 4.6 | 3.7 – 5.5 | mg/L | 1.3 | 1.0 – 1.6 | 4.6 | 3.7 – 5.5 |
| Pharmacia RIA | µg/mL | Δ | | Δ | | mg/L | Δ | | Δ | |
| Roche Cobas Core EIA (2) | ng/mL | 1460 | 1160 – 1750 | 4460 | 3560 – 5350 | mg/L | 1.5 | 1.2 – 1.8 | 4.5 | 3.6 – 5.4 |
| TOSOH AIA-PACK BMG | µg/mL | 1.4 | 1.2 – 1.6 | 5.2 | 4.2 – 6.2 | mg/L | 1.4 | 1.2 – 1.6 | 5.2 | 4.2 – 6.2 |
| UBI Magiwel Quantitative (WHO 1st IS 12/399) (2) | µg/mL | 1.1 | 0.8 – 1.4 | 4.3 | 3.4 – 5.3 | mg/L | 1.1 | 0.8 – 1.4 | 4.3 | 3.4 – 5.3 |
| Wallac AutoDELFIA/DELFIA (2) | µg/mL | 1.2 | 0.8 – 1.6 | 4.4 | 3.3 – 5.5 | mg/L | 1.2 | 0.8 – 1.6 | 4.4 | 3.3 – 5.5 |
| **CALCITONIN** | | | | | | | | | | |
| Diagnostic Products Double Antibody | pg/mL | 136 | 100 – 172 | 546 | 483 – 609 | ng/L | 136 | 100 – 172 | 546 | 483 – 609 |
| Diagnostic Systems Labs Active IRMA (2) | pg/mL | 13 | <10 – 19 | 94 | 60 – 128 | ng/L | 13 | <10 – 19 | 94 | 60 – 128 |
| Diagnostic Systems Labs RIA | pg/mL | 36 | 28 – 43 | 199 | 151 – 246 | ng/L | 36 | 28 – 43 | 199 | 151 – 246 |
| **CA 15-3 (3)** | | | | | | | | | | |
| Abbott AxSYM | U/mL | 12.7 | 10.1 – 15.2 | 47.8 | 38.2 – 57.4 | U/mL | 12.7 | 10.1 – 15.2 | 47.8 | 38.2 – 57.4 |
| Abbott IMx | U/mL | 12.2 | 9.7 – 14.6 | 45.9 | 36.7 – 55.0 | U/mL | 12.2 | 9.7 – 14.6 | 45.9 | 36.7 – 55.0 |
| Adaltis BR-Marker (Automated System) (2) | U/mL | <17.3 | | 37.3 | 30.8 – 43.8 | U/mL | <17.3 | | 37.3 | 30.8 – 43.8 |
| Adaltis BR-Marker Maiaclone (2) | U/mL | <19.4 | | 53.2 | 30.5 – 75.9 | U/mL | <19.4 | | 53.2 | 30.5 – 75.9 |
| Bayer ACS.180 | U/mL | § | | § | | U/mL | § | | § | |
| Bayer Advia Centaur (BR) | U/mL | 11.4 | 9.2 – 13.7 | 58.1 | 46.5 – 69.7 | U/mL | 11.4 | 9.2 – 13.7 | 58.1 | 46.5 – 69.7 |
| Bayer Advia Centaur (Centocor) | U/mL | 12.6 | 10.1 – 15.1 | 51.1 | 40.9 – 61.3 | U/mL | 12.6 | 10.1 – 15.1 | 51.1 | 40.9 – 61.3 |
| Bayer Immuno I | U/mL | 11.6 | 8.7 – 14.5 | 30.3 | 22.7 – 37.9 | U/mL | 11.6 | 8.7 – 14.5 | 30.3 | 22.7 – 37.9 |
| BioCheck EIA (2) | U/mL | 13.0 | 6.0 – 20.0 | 36.8 | 29.9 – 43.8 | U/mL | 13.0 | 6.0 – 20.0 | 36.8 | 29.9 – 43.8 |
| bioMérieux VIDAS (2) | U/mL | 12.5 | 7.3 – 17.7 | 42.0 | 31.0 – 53.0 | U/mL | 12.5 | 7.3 – 17.7 | 42.0 | 31.0 – 53.0 |
| Byk-Sangtec IRMA-mat/RIA-mat 280 (2) | U/mL | 11.3 | 7.1 – 15.5 | 42.9 | 32.0 – 53.8 | U/mL | 11.3 | 7.1 – 15.5 | 42.9 | 32.0 – 53.8 |
| Byk-Sangtec LIA-mat/LIA-mat S300 (2) | U/mL | 14.9 | 9.0 – 20.8 | 49.7 | 33.0 – 66.4 | U/mL | 14.9 | 9.0 – 20.8 | 49.7 | 33.0 – 66.4 |
| Byk-Sangtec LIAISON (2) | U/mL | 14.1 | 11.5 – 16.7 | 50.2 | 40.8 – 59.6 | U/mL | 14.1 | 11.5 – 16.7 | 50.2 | 40.8 – 59.6 |
| CanAg EIA (2) | U/mL | 11.1 | 7.7 – 14.4 | 38.3 | 32.1 – 44.6 | U/mL | 11.1 | 7.7 – 14.4 | 38.3 | 32.1 – 44.6 |
| CIS ELSA | U/mL | Δ | | Δ | | U/mL | Δ | | Δ | |

| | UNITS | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE | SI | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE |
|---|---|---|---|---|---|---|---|---|---|---|
| CA 15-3 (3) (continued) | | | | | | | | | | |
| Immunotech IRMA (2) | U/mL | | <15.0 – 19.2 | 53.2 | 37.2 – 69.2 | U/mL | | <15.0 – 19.2 | 53.2 | 37.2 – 69.2 |
| Ortho Clinical Diagnostics Vitros ECi | U/mL | 13.5 | 9.2 – 17.8 | 44.4 | 31.5 – 57.3 | U/mL | 13.5 | 9.2 – 17.8 | 44.4 | 31.5 – 57.3 |
| Roche Cobas Core EIA (2) | U/mL | 14.9 | 9.9 – 20.0 | 45.4 | 34.2 – 56.6 | U/mL | 14.9 | 9.9 – 20.0 | 45.4 | 34.2 – 56.6 |
| Roche Elecsys | U/mL | 14.5 | 10.1 – 18.8 | 51.9 | 36.3 – 67.5 | U/mL | 14.5 | 10.1 – 18.8 | 51.9 | 36.3 – 67.5 |
| CA 19-9 (3) | | | | | | | | | | |
| Abbott Architect | U/mL | 5.7 | 4.5 – 6.8 | 45.5 | 36.4 – 54.5 | U/mL | 5.7 | 4.5 – 6.8 | 45.5 | 36.4 – 54.5 |
| Abbott AxSYM | U/mL | 7.8 | 6.3 – 9.4 | 42.3 | 33.9 – 50.8 | U/mL | 7.8 | 6.3 – 9.4 | 42.3 | 33.9 – 50.8 |
| Adaltis SR1 (Automated System) (2) | U/mL | 13.5 | 11.0 – 16.1 | 30.5 | 24.3 – 36.6 | U/mL | 13.5 | 11.0 – 16.1 | 30.5 | 24.3 – 36.6 |
| Adaltis Maiaclone (2) | U/mL | <15.0 | | 25.8 | 16.6 – 34.9 | U/mL | <15.0 | | 25.8 | 16.6 – 34.9 |
| Bayer ACS:180 | U/mL | 14.1 | 11.3 – 16.9 | 46.6 | 37.3 – 55.9 | U/mL | 14.1 | 11.3 – 16.9 | 46.6 | 37.3 – 55.9 |
| Bayer Advia Centaur | U/mL | 9.6 | 7.7 – 11.5 | 42.5 | 34.0 – 51.0 | U/mL | 9.6 | 7.7 – 11.5 | 42.5 | 34.0 – 51.0 |
| Bayer Immuno I | U/mL | 9.3 | 7.0 – 11.6 | 62.8 | 47.1 – 78.5 | U/mL | 9.3 | 7.0 – 11.6 | 62.8 | 47.1 – 78.5 |
| BioCheck EIA (2) | U/mL | 10.0 | 7.0 – 14.0 | 29.8 | 21.7 – 38.0 | U/mL | 10.0 | 7.0 – 14.0 | 29.8 | 21.7 – 38.0 |
| bioMérieux VIDAS (2) | U/mL | 7.4 | 4.8 – 10.0 | 37.0 | 29.0 – 45.0 | U/mL | 7.4 | 4.8 – 10.0 | 37.0 | 29.0 – 45.0 |
| Byk-Sangtec IRMA-mat/RIA-mat 280 (2) | U/mL | 6.9 | 4.8 – 8.9 | 39.4 | 32.3 – 46.5 | U/mL | 6.9 | 4.8 – 8.9 | 39.4 | 32.3 – 46.5 |
| Byk-Sangtec LIA-mat (2) | U/mL | 8.3 | 4.9 – 11.7 | 45.0 | 34.9 – 55.1 | U/mL | 8.3 | 4.9 – 11.7 | 45.0 | 34.9 – 55.1 |
| Byk-Sangtec LIAISON (2) | U/mL | 7.9 | 4.8 – 11.1 | 40.1 | 33.6 – 46.6 | U/mL | 7.9 | 4.8 – 11.1 | 40.1 | 33.6 – 46.6 |
| CanAg EIA (2) | U/mL | 8.0 | 5.4 – 10.5 | 27.3 | 22.7 – 31.9 | U/mL | 8.0 | 5.4 – 10.5 | 27.3 | 22.7 – 31.9 |
| CIS ELSA | U/mL | Δ | | Δ | | U/mL | Δ | | Δ | |
| Diagnostic Products Immulite (2) | U/mL | <8.2 | | 28.7 | 18.1 – 39.3 | U/mL | <8.2 | | 28.7 | 18.1 – 39.3 |
| Diagnostic Products Immulite 2000 (2) | U/mL | 7.3 | 5.6 – 9.0 | 29.9 | 23.9 – 35.9 | U/mL | 7.3 | 5.6 – 9.0 | 29.9 | 23.9 – 35.9 |
| FUJIREBIO RIA | U/mL | 9.2 | 7.2 – 11.3 | 40.2 | 37.6 – 43.6 | U/mL | 9.2 | 7.2 – 11.3 | 40.2 | 37.6 – 43.6 |
| Immunotech IRMA (2) | U/mL | <15.0 | | 32.7 | 22.9 – 42.5 | U/mL | <15.0 | | 32.7 | 22.9 – 42.5 |
| Mitsubishi Kagaku Medical (LPIA) (2) | U/mL | 13.7 | 10.9 – 16.5 | 36.2 | 28.9 – 43.5 | U/mL | 13.7 | 10.9 – 16.5 | 36.2 | 28.9 – 43.5 |
| Mitsubishi Kagaku Medical (LPIA-F) (2) | U/mL | 6.7 | 5.3 – 8.1 | 51.3 | 41.0 – 61.6 | U/mL | 6.7 | 5.3 – 8.1 | 51.3 | 41.0 – 61.6 |
| Ortho Clinical Diagnostics Vitros ECi | U/mL | 9.3 | 6.5 – 12.0 | 49.6 | 35.0 – 64.2 | U/mL | 9.3 | 6.5 – 12.0 | 49.6 | 35.0 – 64.2 |
| Roche Cobas Core EIA II (2) | U/mL | 7.1 | 4.7 – 9.5 | 36.2 | 31.3 – 47.0 | U/mL | 7.1 | 4.7 – 9.5 | 36.2 | 31.3 – 47.0 |
| Roche Elecsys | U/mL | 9.4 | 6.9 – 11.9 | 35.5 | 28.0 – 43.0 | U/mL | 9.4 | 6.9 – 11.9 | 35.5 | 28.0 – 43.0 |
| TFB Ranream (2) | U/mL | 11.3 | 9.0 – 13.5 | 45.5 | 36.4 – 54.6 | U/mL | 11.3 | 9.0 – 13.5 | 45.5 | 36.4 – 54.6 |
| TOSOH AIA-PACK IEMA (2) | U/mL | 11.0 | 9.0 – 13.0 | 44.0 | 40.0 – 48.0 | U/mL | 11.0 | 9.0 – 13.0 | 44.0 | 40.0 – 48.0 |
| - 27 29 | | | | | | | | | | |
| Bayer ACS.180 | U/mL | | <3.5 – 5.1 | 50.2 | 40.1 – 60.2 | U/mL | | <3.5 – 5.1 | 50.2 | 40.1 – 60.2 |
| Bayer Advia Centaur | U/mL | | <3.5 – 5.9 | 50.4 | 40.3 – 60.5 | U/mL | | <3.5 – 5.9 | 50.4 | 40.3 – 60.5 |
| TOSOH AIA-PACK IEMA | U/mL | 12.0 | 10.0 – 14.0 | 45.0 | 38.0 – 52.0 | U/mL | 12.0 | 10.0 – 14.0 | 45.0 | 38.0 – 52.0 |
| - 50 | | | | | | | | | | |
| CIS RIA gnost | U/mL | Δ | | Δ | | U/mL | Δ | | Δ | |
| 72-4 (3) | | | | | | | | | | |
| Bayer Immuno I | U/mL | 6.3 | 5.1 – 7.5 | 21.1 | 16.9 – 25.3 | U/mL | 6.3 | 5.1 – 7.5 | 21.1 | 16.9 – 25.3 |
| Byk-Sangtec IRMA-mat (2) | U/mL | 5.5 | 3.7 – 7.2 | 9.9 | 7.1 – 12.7 | U/mL | 5.5 | 3.7 – 7.2 | 9.9 | 7.1 – 12.7 |
| Byk-Sangtec LIA-mat/LIA-mat S300 (2) | U/mL | 7.8 | 5.7 – 9.9 | 12.6 | 8.2 – 17.0 | U/mL | 7.8 | 5.7 – 9.9 | 12.6 | 8.2 – 17.0 |
| CIS ELSA | U/mL | Δ | | Δ | | U/mL | Δ | | Δ | |
| FUJIREBIO RIA (2) | U/mL | 5.4 | 4.8 – 6.2 | 9.4 | 7.7 – 10.6 | U/mL | 5.4 | 4.8 – 6.2 | 9.4 | 7.7 – 10.6 |
| Roche Cobas Core EIA (2) | U/mL | 3.6 | 1.8 – 5.4 | 9.9 | 5.7 – 14.0 | U/mL | 3.6 | 1.8 – 5.4 | 9.9 | 5.7 – 14.0 |
| Roche Elecsys | U/mL | 5.9 | 4.7 – 7.2 | 11.8 | 9.3 – 14.3 | U/mL | 5.9 | 4.7 – 7.2 | 11.8 | 9.3 – 14.3 |
| 125 (3) | | | | | | | | | | |
| Abbott AxSYM | U/mL | 35 | 28 – 42 | 90 | 72 – 108 | U/mL | 35 | 28 – 42 | 90 | 72 – 108 |
| Abbott IMx | U/mL | § | | § | | U/mL | § | | § | |
| Adaltis SR1 (Automated System) (2) | U/mL | 27 | 21 – 32 | 63 | 49 – 77 | U/mL | 27 | 21 – 32 | 63 | 49 – 77 |
| Adaltis Maiaclone (2) | U/mL | 25 | 16 – 34 | 81 | 54 – 108 | U/mL | 25 | 16 – 34 | 81 | 54 – 108 |
| Bayer ACS:180 | U/mL | 42 | 33 – 50 | 123 | 98 – 147 | U/mL | 42 | 33 – 50 | 123 | 98 – 147 |
| Bayer Advia Centaur (OV) | U/mL | 51 | 40 – 61 | 144 | 115 – 173 | U/mL | 51 | 40 – 61 | 144 | 115 – 173 |
| Bayer Advia Centaur (Centocor) | U/mL | 34 | 27 – 41 | 89 | 71 – 106 | U/mL | 34 | 27 – 41 | 89 | 71 – 106 |
| Bayer Immuno I | U/mL | 22 | 16 – 28 | 78 | 58 – 98 | U/mL | 22 | 16 – 28 | 78 | 58 – 98 |
| BioCheck EIA (2) | U/mL | 35 | 30 – 41 | 97 | 81 – 113 | U/mL | 35 | 30 – 41 | 97 | 81 – 113 |
| bioMérieux VIDAS II (2) | U/mL | 22 | 16 – 28 | 65 | 51 – 79 | U/mL | 22 | 16 – 28 | 65 | 51 – 79 |
| Byk-Sangtec IRMA-mat/RIA-mat 280 II (2) | U/mL | 27 | 23 – 31 | 75 | 64 – 86 | U/mL | 27 | 23 – 31 | 75 | 64 – 86 |
| Byk-Sangtec LIA-mat/LIA-mat S300 II (2) | U/mL | 29 | 22 – 36 | 76 | 60 – 93 | U/mL | 29 | 22 – 36 | 76 | 60 – 93 |
| Byk-Sangtec LIAISON II (2) | U/mL | 37 | 30 – 44 | 101 | 84 – 118 | U/mL | 37 | 30 – 44 | 101 | 84 – 118 |
| CanAg EIA (2) | U/mL | 30 | 25 – 35 | 78 | 66 – 90 | U/mL | 30 | 25 – 35 | 78 | 66 – 90 |
| CIS ELSA II | U/mL | Δ | | Δ | | U/mL | Δ | | Δ | |
| Diagnostic Products Immulite | U/mL | 31 | 26 – 36 | 84 | 70 – 98 | U/mL | 31 | 26 – 36 | 84 | 70 – 98 |
| Diagnostic Products Immulite 2000 | U/mL | 27 | 23 – 31 | 72 | 65 – 79 | U/mL | 27 | 23 – 31 | 72 | 65 – 79 |
| FUJIREBIO RIA II | U/mL | 27 | 25 – 29 | 70 | 64 – 75 | U/mL | 27 | 25 – 29 | 70 | 64 – 75 |
| Immunotech IRMA (2) | U/mL | 25 | 20 – 30 | 72 | 58 – 86 | U/mL | 25 | 20 – 30 | 72 | 58 – 86 |
| Ortho Clinical Diagnostics Vitros ECi | U/mL | 24 | 19 – 30 | 67 | 52 – 83 | U/mL | 24 | 19 – 30 | 67 | 52 – 83 |
| Roche Cobas Core EIA II (2) | U/mL | 41 | 33 – 49 | 105 | 84 – 126 | U/mL | 41 | 33 – 49 | 105 | 84 – 126 |
| Roche Elecsys | U/mL | 30 | 23 – 36 | 78 | 62 – 94 | U/mL | 30 | 23 – 36 | 78 | 62 – 94 |
| TFB Ranream II (2) | U/mL | 30 | 24 – 35 | 86 | 69 – 103 | U/mL | 30 | 24 – 35 | 86 | 69 – 103 |
| TOSOH AIA-PACK IEMA | U/mL | 35 | 30 – 40 | 98 | 84 – 112 | U/mL | 35 | 30 – 40 | 98 | 84 – 112 |
| BI Magiwel (2) | U/mL | 21 | 16 – 25 | 62 | 50 – 75 | U/mL | 21 | 16 – 25 | 62 | 50 – 75 |
| ARCINOEMBRYONIC ANTIGEN) | | | | | | | | | | |
| bbott Architect | ng/mL | 3.5 | 2.8 – 4.2 | 30.3 | 24.2 – 36.4 | µg/L | 3.5 | 2.8 – 4.2 | 30.3 | 24.2 – 36.4 |
| bbott AxSYM | ng/mL | 4.4 | 3.5 – 5.3 | 35.1 | 28.1 – 42.1 | µg/L | 4.4 | 3.5 – 5.3 | | |
| bbott IMx | | | | | | | | | | |

| | UNITS | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE | SI | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE |
|---|---|---|---|---|---|---|---|---|---|---|
| CARCINOEMBRYONIC ANTIGEN) (continued) | | | | | | | | | | |
| Adaltis BRIDGE (2) | ng/mL | 2.5 | 1.6 – 3.4 | 18.4 | 13.5 – 23.4 | µg/L | 2.5 | 1.6 – 3.4 | 18.4 | 13.5 – 23.4 |
| Bayer ACS:180 | ng/mL | 2.3 | 1.8 – 2.7 | 14.3 | 11.4 – 17.2 | µg/L | 2.3 | 1.8 – 2.7 | 14.3 | 11.4 – 17.2 |
| Bayer Advia Centaur | ng/mL | 2.0 | 1.6 – 2.4 | 12.6 | 10.1 – 15.1 | µg/L | 2.0 | 1.6 – 2.4 | 12.6 | 10.1 – 15.1 |
| Bayer Immuno 1 | ng/mL | 1.9 | 1.5 – 2.3 | 23.1 | 18.5 – 27.7 | µg/L | 1.9 | 1.5 – 2.3 | 23.1 | 18.5 – 27.7 |
| Beckman Coulter ACCESS | ng/mL | 1.7 | 1.4 – 2.0 | 12.1 | 10.1 – 14.0 | µg/L | 1.7 | 1.4 – 2.0 | 12.1 | 10.1 – 14.0 |
| BioCheck EIA (2) | ng/mL | 4.3 | 4.0 – 5.2 | 28.0 | 26.7 – 31.7 | µg/L | 4.3 | 4.0 – 5.2 | 28.0 | 26.7 – 31.7 |
| bioMérieux VIDAS (2) | ng/mL | 1.9 | 1.2 – 2.6 | 15.5 | 10.5 – 20.5 | µg/L | 1.9 | 1.2 – 2.6 | 15.5 | 10.5 – 20.5 |
| Byk-Sangtec IRMA-coat/RIA-mat 280 (2) | ng/mL | 7.6 | 5.8 – 9.4 | 61.0 | 51.1 – 70.9 | µg/L | 7.6 | 5.8 – 9.4 | 61.0 | 51.1 – 70.9 |
| Byk-Sangtec LIA-mat/LIA-mat S300 (2) | ng/mL | 2.0 | 1.4 – 2.7 | 15.4 | 12.8 – 18.0 | µg/L | 2.0 | 1.4 – 2.7 | 15.4 | 12.8 – 18.0 |
| Byk-Sangtec LIAISON (2) | ng/mL | 2.4 | 1.9 – 2.8 | 13.1 | 11.1 – 15.1 | µg/L | 2.4 | 1.9 – 2.8 | 13.1 | 11.1 – 15.1 |
| CanAg EIA (2) | ng/mL | 6.8 | 5.8 – 7.8 | 56.0 | 47.6 – 64.4 | µg/L | 6.8 | 5.8 – 7.8 | 56.0 | 47.6 – 64.4 |
| Diagnostic Products Coat-A-Count IRMA (2) | ng/mL | 3.6 | <3.0 – 5.0 | 27.5 | 23.9 – 31.1 | µg/L | 3.6 | <3.0 – 5.0 | 27.5 | 23.9 – 31.1 |
| Diagnostic Products Immulite | ng/mL | 3.9 | 3.2 – 4.6 | 35.1 | 30.6 – 39.6 | µg/L | 3.9 | 3.2 – 4.6 | 35.1 | 30.6 – 39.6 |
| Diagnostic Products Immulite 2000 | ng/mL | 4.2 | 3.6 – 4.8 | 37.1 | 32.2 – 42.0 | µg/L | 4.2 | 3.6 – 4.8 | 37.1 | 32.2 – 42.0 |
| DiaSorin M-K-S (2) | ng/mL | 5.1 | 3.6 – 6.7 | 41.5 | 31.2 – 51.9 | µg/L | 5.1 | 3.6 – 6.7 | 41.5 | 31.2 – 51.9 |
| Immunotech IRMA (2) | ng/mL | 2.1 | 1.5 – 2.8 | 14.8 | 11.8 – 17.8 | µg/L | 2.1 | 1.5 – 2.8 | 14.8 | 11.8 – 17.8 |
| Mitsubishi Kagaku Medical (LPIA) (2) | ng/mL | 3.5 | 2.8 – 4.3 | 24.2 | 19.3 – 29.1 | µg/L | 3.5 | 2.8 – 4.3 | 24.2 | 19.3 – 29.1 |
| Mitsubishi Kagaku Medical (LPIA-F) (2) | ng/mL | 1.5 | 1.1 – 1.8 | 10.3 | 8.2 – 12.4 | µg/L | 1.5 | 1.1 – 1.8 | 10.3 | 8.2 – 12.4 |
| Ortho Clinical Diagnostics Vitros ECi (1st IRP 73/601) | ng/mL | 6.0 | 4.6 – 7.5 | 53.5 | 40.5 – 66.5 | µg/L | 6.0 | 4.6 – 7.5 | 53.5 | 40.5 – 66.5 |
| RADIM BRIO (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| RADIM IRMA CT (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Roche Cobas Core EIA II (2) | ng/mL | 3.7 | 2.8 – 4.6 | 26.1 | 18.9 – 33.4 | µg/L | 3.7 | 2.8 – 4.6 | 26.1 | 18.9 – 33.4 |
| Roche Elecsys | ng/mL | 5.5 | 4.2 – 6.8 | 42.2 | 33.3 – 51.1 | µg/L | 5.5 | 4.2 – 6.8 | 42.2 | 33.3 – 51.1 |
| SOSOH AIA-PACK IEMA (1st IRP 73/601) | ng/mL | 9.3 | 7.7 – 10.9 | 76.0 | 63.0 – 89.0 | µg/L | 9.3 | 7.7 – 10.9 | 76.0 | 63.0 – 89.0 |
| SPI Magiwel Quantitative (2) | ng/mL | 4.1 | 3.1 – 5.1 | 30.6 | 24.3 – 36.8 | µg/L | 4.1 | 3.1 – 5.1 | 30.6 | 24.3 – 36.8 |
| Wallac AutoDELFIA/DELFIA (WHO 1st IRP 73/601) (2) | ng/mL | 5.2 | 3.6 – 6.8 | 41.1 | 32.9 – 49.3 | µg/L | 5.2 | 3.6 – 6.8 | 41.1 | 32.9 – 49.3 |
| CA 21-1 (4) | | | | | | | | | | |
| CIS ELSA (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| IMMUNEBIO RIA (2) | ng/mL | 3.70 | 3.10 – 4.30 | 37 | 35 – 45 | µg/L | 3.70 | 3.10 – 4.30 | 37 | 35 – 45 |
| Roche Elecsys (2) | ng/mL | 4.64 | 3.67 – 5.62 | 35 | 28 – 43 | µg/L | 4.64 | 3.67 – 5.62 | 35 | 28 – 43 |
| CYFRA 21-1 | | | | | | | | | | |
| Abbott Architect | ng/mL | 45 | 36 – 54 | 356 | 285 – 427 | µg/L | 45 | 36 – 54 | 356 | 285 – 427 |
| Adaltis SR1 (Automated System) (2) | ng/mL | 37 | 23 – 52 | 272 | 169 – 374 | µg/L | 37 | 23 – 52 | 272 | 169 – 374 |
| Bayer ACS:180 | ng/mL | 46 | 37 – 56 | 323 | 259 – 388 | µg/L | 46 | 37 – 56 | 323 | 259 – 388 |
| Bayer Advia Centaur | ng/mL | 47 | 37 – 56 | 334 | 267 – 401 | µg/L | 47 | 37 – 56 | 334 | 267 – 401 |
| Bayer Immuno 1 | ng/mL | 41 | 33 – 49 | 298 | 253 – 342 | µg/L | 41 | 33 – 49 | 298 | 253 – 342 |
| BioCheck EIA | ng/mL | 44 | 36 – 51 | 269 | 229 – 310 | µg/L | 44 | 36 – 51 | 269 | 229 – 310 |
| bioMérieux VIDAS | ng/mL | 52 | 32 – 72 | 357 | 272 – 442 | µg/L | 52 | 32 – 72 | 357 | 272 – 442 |
| CIS-Rad Quantimune IRMA | ng/mL | 45 | 36 – 55 | 367 | 278 – 456 | µg/L | 45 | 36 – 55 | 367 | 278 – 456 |
| Byk-Sangtec IRMA-mat/RIA-mat 280 2nd IS 80/578) (2) | ng/mL | 49 | 44 – 55 | 335 | 289 – 381 | µg/L | 49 | 44 – 55 | 335 | 289 – 381 |
| Byk-Sangtec LIAISON (2nd IS 80/578) (2) | ng/mL | 47 | 42 – 53 | 382 | 338 – 426 | µg/L | 47 | 42 – 53 | 382 | 338 – 426 |
| Diagnostic Products Coat-A-Count IRMA | ng/mL | 47 | 38 – 56 | 270 | 182 – 359 | µg/L | 47 | 38 – 56 | 270 | 182 – 359 |
| Diagnostic Products Immulite | ng/mL | 49 | 40 – 58 | 301 | 254 – 348 | µg/L | 49 | 40 – 58 | 301 | 254 – 348 |
| Diagnostic Products Immulite 2000 | ng/mL | 53 | 47 – 59 | 323 | 283 – 363 | µg/L | 53 | 47 – 59 | 323 | 283 – 363 |
| Immunotech IRMA (2) | ng/mL | 44 | 36 – 53 | 261 | 209 – 313 | µg/L | 44 | 36 – 53 | 261 | 209 – 313 |
| Ortho Clinical Diagnostics Vitros ECi | ng/mL | 45 | 34 – 56 | 243 | 178 – 308 | µg/L | 45 | 34 – 56 | 243 | 178 – 308 |
| RADIM BRIO (WHO/MRC 80/602) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| RADIM IRMA CT (WHO/MRC 80/602) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Roche Cobas Core EIA (2) | ng/mL | 46 | 37 – 55 | 402 | 322 – 483 | µg/L | 46 | 37 – 55 | 402 | 322 – 483 |
| Roche Elecsys | ng/mL | 52 | 39 – 64 | 329 | 250 – 408 | µg/L | 52 | 39 – 64 | 329 | 250 – 408 |
| SOSOH AIA-PACK IEMA (1st IS 80/602) | ng/mL | 42 | 35 – 49 | 283 | 251 – 315 | µg/L | 42 | 35 – 49 | 283 | 251 – 315 |
| SPI Magiwel Quantitative (NIBSC 94/572) | ng/mL | 32 | 26 – 38 | 265 | 219 – 311 | µg/L | 32 | 26 – 38 | 265 | 219 – 311 |
| HUMAN CHORIONIC GONADOTROPIN) | | | | | | | | | | |
| Abbott IMx | mIU/mL | 11.0 | 9.2 – 12.8 | 106 | 91 – 121 | IU/L | 11.0 | 9.2 – 12.8 | 106 | 91 – 121 |
| Adaltis SR1 (Automated System) | mIU/mL | 12.7 | 8.8 – 16.6 | 127 | 79 – 175 | IU/L | 12.7 | 8.8 – 16.6 | 127 | 79 – 175 |
| Adaltis Maiaclone | mIU/mL | 16.4 | 10.9 – 21.9 | 152 | 100 – 204 | IU/L | 16.4 | 10.9 – 21.9 | 152 | 100 – 204 |
| Bayer Advia Centaur | mIU/mL | 10.0 | 8.0 – 12.0 | 107 | 85 – 128 | IU/L | 10.0 | 8.0 – 12.0 | 107 | 85 – 128 |
| Bayer Immuno 1 | mIU/mL | 13.1 | 11.2 – 15.1 | 128 | 109 – 148 | IU/L | 13.1 | 11.2 – 15.1 | 128 | 109 – 148 |
| bioMérieux VIDAS (1st IRP 75/537) | mIU/mL | 12.0 | 8.0 – 16.0 | 132 | 104 – 160 | IU/L | 12.0 | 8.0 – 16.0 | 132 | 104 – 160 |
| Byk-Sangtec LIAISON (1st IRP 75/537) (2) | mIU/mL | 6.3 | 4.5 – 8.1 | 77 | 60 – 93 | IU/L | 6.3 | 4.5 – 8.1 | 77 | 60 – 93 |
| DELFIA gnost (1st IRP OMS 75/537) | mIU/mL | Δ | | Δ | | IU/L | Δ | | Δ | |
| Diagnostic Products Coat-A-Count IRMA | mIU/mL | 14.1 | 12.2 – 16.0 | 127 | 115 – 139 | IU/L | 14.1 | 12.2 – 16.0 | 127 | 115 – 139 |
| Diagnostic Products Immulite | mIU/mL | 14.1 | 11.5 – 16.7 | 150 | 134 – 166 | IU/L | 14.1 | 11.5 – 16.7 | 150 | 134 – 166 |
| Diagnostic Products Immulite Turbo | mIU/mL | 14.2 | 12.0 – 16.5 | 152 | 133 – 171 | IU/L | 14.2 | 12.0 – 16.5 | 152 | 133 – 171 |
| Diagnostic Products Immulite 2000 | mIU/mL | 14.7 | 11.2 – 18.2 | 160 | 138 – 182 | IU/L | 14.7 | 11.2 – 18.2 | 160 | 138 – 182 |
| Immunotech IRMA (2) | mIU/mL | 9.0 | 6.3 – 11.7 | 87 | 70 – 104 | IU/L | 9.0 | 6.3 – 11.7 | 87 | 70 – 104 |
| SOSOH AIA-PACK IEMA (3rd IS 75/537) | mIU/mL | 14.3 | 12.9 – 15.7 | 145 | 130 – 160 | IU/L | 14.3 | 12.9 – 15.7 | 145 | 130 – 160 |
| SPI Magiwel Quantitative (WHO 3rd IS 75/537) | mIU/mL | 12.5 | 10.3 – 14.7 | 126 | 102 – 149 | IU/L | 12.5 | 10.3 – 14.7 | 126 | 102 – 149 |
| SUBUNIT | | | | | | | | | | |
| Abbott Architect | mIU/mL | 8.4 | 6.7 – 10.1 | 83 | 67 – 100 | IU/L | 8.4 | 6.7 – 10.1 | 83 | 67 – 100 |
| Abbott AxSYM | mIU/mL | 13.0 | 11.0 – 15.0 | 139 | 125 – 153 | IU/L | 13.0 | 11.0 – 15.0 | 139 | 125 – 153 |
| Abbott IMx | mIU/mL | 12.2 | 9.0 – 15.0 | 136 | 115 – 157 | IU/L | 12.2 | 9.0 – 15.0 | 136 | 115 – 157 |
| Bayer ACS.180 | mIU/mL | 11.3 | 9.0 – 13.5 | 121 | 97 – 145 | IU/L | 11.3 | 9.0 – 13.5 | 121 | 97 – 145 |
| Bayer Advia Centaur | mIU/mL | 11.1 | 8.9 – 13.3 | 120 | 96 – 144 | IU/L | 11.1 | 8.9 – 13.3 | 120 | 96 – 144 |
| Ortho Clinical Diagnostics Vitros ECi (3rd IS 75/537) | mIU/mL | 13.7 | 9.8 – 17.6 | 143 | 102 – 184 | IU/L | 13.7 | 9.8 – 17.6 | 143 | 102 – 184 |
| RADIM BRIO (WHO 61/6) (2) | mIU/mL | Δ | | Δ | | IU/L | Δ | | Δ | |

| | UNITS | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE | SI | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE |
|---|---|---|---|---|---|---|---|---|---|---|
| **hCG-BETA SUBUNIT (continued)** | | | | | | | | | | |
| RADIM IRMA CT (WHO 75/537) (2) | mIU/mL | Δ | | Δ | | IU/L | Δ | | Δ | |
| Roche Cobas Core EIA II (2) | mIU/mL | 9.6 | 5.7 – 13.4 | 94 | 75 – 112 | IU/L | 9.6 | 5.7 – 13.4 | 94 | 75 – 112 |
| TOSOH AIA-PACK IEMA (3rd IS 75/537) | mIU/mL | 14.5 | 12.0 – 16.0 | 143 | 121 – 165 | IU/L | 14.5 | 12.0 – 16.0 | 143 | 121 – 165 |
| **NSE (NEURON SPECIFIC ENOLASE)** | | | | | | | | | | |
| Byk Sangtec LIA-mat Prolifigen (2) | ng/mL | 7.10 | 4.25 – 9.95 | 22.6 | 16.3 – 28.9 | µg/L | 7.10 | 4.25 – 9.95 | 22.6 | 16.3 – 28.9 |
| Byk Sangtec LIAISON (2) | ng/mL | 5.47 | 4.88 – 6.05 | 25.9 | 23.3 – 28.5 | µg/L | 5.47 | 4.88 – 6.05 | 25.9 | 23.3 – 28.5 |
| Byk Sangtec Prolifigen IRMA (2) | ng/mL | 5.70 | 3.90 – 7.50 | 17.5 | 10.9 – 24.1 | µg/L | 5.70 | 3.90 – 7.50 | 17.5 | 10.9 – 24.1 |
| CanAg EIA (2) | ng/mL | < 5.00 | | 23.5 | 20.0 – 27.0 | µg/L | < 5.00 | | 23.5 | 20.0 – 27.0 |
| CIS ELSA | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Pharmacia RIA (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Roche Cobas Core EIA II (2) | ng/mL | 2.84 | 1.10 – 4.59 | 23.8 | 18.2 – 29.4 | µg/L | 2.84 | 1.10 – 4.59 | 23.8 | 18.2 – 29.4 |
| Roche Elecsys | ng/mL | 1.37 | 1.08 – 1.66 | 21.0 | 16.6 – 25.4 | µg/L | 1.37 | 1.08 – 1.66 | 21.0 | 16.6 – 25.4 |
| **PAP (PROSTATIC ACID PHOSPHATASE)** | | | | | | | | | | |
| Abbott IMx | ng/mL | 0.85 | 0.68 – 1.02 | 2.3 | 1.8 – 2.7 | µg/L | 0.85 | 0.68 – 1.02 | 2.3 | 1.8 – 2.7 |
| Diagnostic Products IRMA Coat-A-Count | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Diagnostic Products Immulite | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Diagnostic Products Immulite 2000 | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| TOSOH AIA-PACK IEMA | ng/mL | 0.40 | 0.20 – 0.60 | 1.5 | 1.0 – 2.0 | µg/L | 0.40 | 0.20 – 0.60 | 1.5 | 1.0 – 2.0 |
| UBI Magiwel Quantitative | ng/mL | < 0.50 | | 1.3 | 0.9 – 1.5 | µg/L | < 0.50 | | 1.3 | 0.9 – 1.5 |
| **PROLACTIN** | | | | | | | | | | |
| Abbott Architect | ng/mL | 20.2 | 16.1 – 24.2 | 127 | 102 – 153 | µg/L | 20.2 | 16.1 – 24.2 | 127 | 102 – 153 |
| Abbott AxSYM | ng/mL | 21.0 | 18.0 – 24.0 | 144 | 119 – 169 | µg/L | 21.0 | 18.0 – 24.0 | 144 | 119 – 169 |
| Abbott IMx | ng/mL | 21.0 | 17.0 – 25.0 | 144 | 120 – 168 | µg/L | 21.0 | 17.0 – 25.0 | 144 | 120 – 168 |
| Adaltis SR1 (Automated System) | µIU/mL | 354 | 283 – 425 | 1751 | 1391 – 2112 | µIU/mL | 354 | 283 – 425 | 1751 | 1391 – 2112 |
| Adaltis Maiaclone | ng/mL | 19.9 | 12.8 – 27.0 | 123 | 76 – 170 | µIU/mL | 398 | 257 – 540 | 2468 | 1528 – 3408 |
| Bayer ACS 180 | ng/mL | 16.3 | 13.1 – 19.6 | 109 | 87 – 131 | µg/L | 16.3 | 13.1 – 19.6 | 109 | 87 – 131 |
| Bayer Advia Centaur | ng/mL | 15.1 | 12.1 – 18.1 | 97 | 77 – 116 | µg/L | 15.1 | 12.1 – 18.1 | 97 | 77 – 116 |
| Bayer Immuno 1 | ng/mL | 12.4 | 9.9 – 14.9 | 81 | 69 – 93 | µg/L | 12.4 | 9.9 – 14.9 | 81 | 69 – 93 |
| BioCheck EIA | ng/mL | 28.5 | 24.8 – 32.3 | 170 | 136 – 203 | µg/L | 28.5 | 24.8 – 32.3 | 170 | 136 – 203 |
| Byk-Sangtec IRMA-mat/RIA-mat 280 (3rd IS 84/500) (2) | µIU/mL | 404 | 352 – 456 | 2693 | 2220 – 3166 | mIU/L | 404 | 352 – 456 | 2693 | 2220 – 3166 |
| Byk-Sangtec LIA-mat/LIA-mat S300 (3rd IS 84/500) (2) | µIU/mL | 428 | 358 – 498 | 2712 | 2014 – 3410 | mIU/L | 428 | 358 – 498 | 2712 | 2014 – 3410 |
| Byk-Sangtec LIAISON (3rd IS 84/500) (2) | µIU/mL | 346 | 297 – 395 | 2244 | 2004 – 2484 | mIU/L | 346 | 297 – 395 | 2244 | 2004 – 2484 |
| CIS RIA gnost | µIU/mL | Δ | | Δ | | mIU/L | Δ | | Δ | |
| Diagnostic Products Coat-A-Count | ng/mL | 11.5 | 9.6 – 13.4 | 89 | 81 – 97 | µg/L | 11.5 | 9.6 – 13.4 | 89 | 81 – 97 |
| Diagnostic Products IRMA Coat-A-Count | ng/mL | 15.2 | 13.3 – 17.1 | 100 | 83 – 117 | µg/L | 15.2 | 13.3 – 17.1 | 100 | 83 – 117 |
| Diagnostic Products Immulite | ng/mL | 15.2 | 13.6 – 16.8 | 104 | 93 – 115 | µg/L | 15.2 | 13.6 – 16.8 | 104 | 93 – 115 |
| Diagnostic Products Immulite 2000 | ng/mL | 14.8 | 13.2 – 16.4 | 102 | 87 – 117 | µg/L | 14.8 | 13.2 – 16.4 | 102 | 87 – 117 |
| Immunotech IRMA (WHO 84/500) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Ortho Clinical Diagnostics Vitros ECi (3rd IS 84/500) | µIU/mL | 361 | 268 – 454 | 2273 | 1673 – 2873 | mIU/L | 361 | 268 – 454 | 2273 | 1673 – 2873 |
| RADIM BRIO (WHO 75/504) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| RADIM IRMA CT (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Roche Cobas Core EIA (2) | µIU/mL | 494 | 395 – 593 | 3710 | 2960 – 4450 | mIU/L | 494 | 395 – 593 | 3710 | 2960 – 4450 |
| Roche Elecsys | µIU/mL | 494 | 376 – 613 | 3043 | 2313 – 3774 | mIU/L | 494 | 376 – 613 | 3043 | 2313 – 3774 |
| TOSOH AIA-PACK IEMA (2nd IS 83/562) | ng/mL | 16.8 | 14.8 – 18.8 | 112 | 102 – 122 | µg/L | 16.8 | 14.8 – 18.8 | 112 | 102 – 122 |
| UBI Magiwel Quantitative (NIBSC 81/541) | ng/mL | 24.5 | 19.8 – 29.2 | 106 | 88 – 123 | µg/L | 24.5 | 19.8 – 29.2 | 106 | 88 – 123 |
| **PSA (PROSTATE SPECIFIC ANTIGEN)** | | | | | | | | | | |
| Abbott Architect | ng/mL | 1.8 | 1.4 – 2.2 | 22 | 17 – 26 | µg/L | 1.8 | 1.4 – 2.2 | 22 | 17 – 26 |
| Abbott AxSYM (MEIA) (Mono/Mono Kit # 3C19) | ng/mL | 1.7 | 1.3 – 2.0 | 21 | 17 – 25 | µg/L | 1.7 | 1.3 – 2.0 | 21 | 17 – 25 |
| Abbott AxSYM (MEIA) (Mono/Poly Kit # 7A49) | ng/mL | 3.8 | 3.0 – 4.5 | 46 | 37 – 55 | µg/L | 3.8 | 3.0 – 4.5 | 46 | 37 – 55 |
| Abbott IMx | ng/mL | 3.7 | 3.0 – 4.5 | 47 | 38 – 56 | µg/L | 3.7 | 3.0 – 4.5 | 47 | 38 – 56 |
| Adaltis SR1 (Automated System) (2) | ng/mL | 1.7 | 1.2 – 2.1 | 29 | 23 – 34 | µg/L | 1.7 | 1.2 – 2.1 | 29 | 23 – 34 |
| Adaltis Maiaclone (2) | ng/mL | 2.3 | 1.4 – 3.1 | 26 | 21 – 31 | µg/L | 2.3 | 1.4 – 3.1 | 26 | 21 – 31 |
| Bayer ACS 180 (Equimolar) | ng/mL | 2.2 | 1.7 – 2.6 | 24 | 19 – 29 | µg/L | 2.2 | 1.7 – 2.6 | 24 | 19 – 29 |
| Bayer Advia Centaur (Equimolar) | ng/mL | 1.9 | 1.5 – 2.2 | 21 | 17 – 26 | µg/L | 1.9 | 1.5 – 2.2 | 21 | 17 – 26 |
| Bayer Immuno I | ng/mL | 2.1 | 1.7 – 2.5 | 29 | 23 – 34 | µg/L | 2.1 | 1.7 – 2.5 | 29 | 23 – 34 |
| Beckman Coulter ACCESS Hybritech | ng/mL | 2.9 | 2.4 – 3.4 | 34 | 28 – 39 | µg/L | 2.9 | 2.4 – 3.4 | 34 | 28 – 39 |
| BioCheck EIA (2) | ng/mL | 5.0 | 3.1 – 6.9 | 69 | 47 – 91 | µg/L | 5.0 | 3.1 – 6.9 | 69 | 47 – 91 |
| bioMérieux VIDAS | ng/mL | 2.6 | 1.8 – 3.4 | 29 | 24 – 34 | µg/L | 2.6 | 1.8 – 3.4 | 29 | 24 – 34 |
| Byk-Sangtec IRMA-mat/RIA-mat 280 (2) | ng/mL | 2.1 | 1.6 – 2.6 | 27 | 21 – 32 | µg/L | 2.1 | 1.6 – 2.6 | 27 | 21 – 32 |
| Byk-Sangtec LIA-mat/LIA-mat S300 (2) | ng/mL | 2.7 | 2.1 – 3.2 | 33 | 27 – 39 | µg/L | 2.7 | 2.1 – 3.2 | 33 | 27 – 39 |
| Byk-Sangtec LIAISON (2) | ng/mL | 2.1 | 1.7 – 2.5 | 27 | 23 – 31 | µg/L | 2.1 | 1.7 – 2.5 | 27 | 23 – 31 |
| CanAg EIA (2) | ng/mL | 2.2 | 1.7 – 2.7 | 27 | 23 – 31 | µg/L | 2.2 | 1.7 – 2.7 | 27 | 23 – 31 |
| CIS RIA CT | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Dade Behring Dimension (TPSA) | ng/mL | 1.8 | 1.2 – 2.3 | 22 | 15 – 29 | µg/L | 1.8 | 1.2 – 2.3 | 22 | 15 – 29 |
| Diagnostic Products Coat-A-Count IRMA | ng/mL | 1.8 | <1.5 – 2.3 | 24 | 20 – 27 | µg/L | 1.8 | <1.5 – 2.3 | 24 | 20 – 27 |
| Diagnostic Products Immulite | ng/mL | 2.9 | 2.3 – 3.5 | 32 | 28 – 36 | µg/L | 2.9 | 2.3 – 3.5 | 32 | 28 – 36 |
| Diagnostic Products Immulite 3rd Gen. | ng/mL | 2.2 | 1.9 – 2.5 | >20 | | µg/L | 2.2 | 1.9 – 2.5 | >20 | |
| Diagnostic Products Immulite 2000 | ng/mL | 2.8 | 2.4 – 3.1 | 33 | 29 – 37 | µg/L | 2.8 | 2.4 – 3.1 | 33 | 29 – 37 |
| Diagnostic Products Immulite 2000 3rd Gen. | ng/mL | 2.3 | 1.9 – 2.6 | >20 | | µg/L | 2.3 | 1.9 – 2.6 | >20 | |
| Immunotech IRMA (2) | ng/mL | 1.8 | 1.4 – 2.2 | 22 | 17 – 26 | µg/L | 1.8 | 1.4 – 2.2 | 22 | 17 – 26 |
| Ortho Clinical Diagnostics Vitros ECi | ng/mL | 2.1 | 1.5 – 2.7 | 22 | 17 – 27 | µg/L | 2.1 | 1.5 – 2.7 | 22 | 17 – 27 |
| Roche Cobas Core EIA II (2) | ng/mL | 2.2 | 1.5 – 3.0 | 29 | 21 – 37 | µg/L | 2.2 | 1.5 – 3.0 | 29 | 21 – 37 |
| Roche Elecsys | ng/mL | 2.6 | 1.9 – 3.4 | 31 | 22 – 40 | µg/L | 2.6 | 1.9 – 3.4 | 31 | 22 – 40 |
| TOSOH AIA-PACK IEMA | ng/mL | 2.4 | 2.1 – 2.7 | 28 | 24 – 32 | µg/L | 2.4 | 2.1 – 2.7 | 28 | 24 – 32 |
| UBI Magiwel Quantitative (2) | ng/mL | | | | | | | | | |

| | UNITS | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE | SI | LEVEL 1 – 44111 MEAN | LEVEL 1 – 44111 RANGE | LEVEL 2 – 44112[1] MEAN | LEVEL 2 – 44112[1] RANGE |
|---|---|---|---|---|---|---|---|---|---|---|
| -ROSTATE SPECIFIC ANTIGEN) (continued) | | | | | | | | | | |
| llac AutoDELFIA/DELFIA Prostatus EQM (2) | ng/mL | 1.9 | 1.5 – 2.3 | 22 | 18 – 26 | µg/L | 1.9 | 1.5 – 2.3 | 22 | 18 – 26 |
| llac AutoDELFIA/DELFIA Prostatus Total (2) | ng/mL | 1.9 | 1.5 – 2.3 | 21 | 17 – 25 | µg/L | 1.9 | 1.5 – 2.3 | 21 | 17 – 25 |
| SA | | | | | | | | | | |
| ɔott Architect | ng/mL | 1.9 | 1.5 – 2.3 | 24 | 20 – 29 | µg/L | 1.9 | 1.5 – 2.3 | 24 | 20 – 29 |
| ɔott AxSYM (2) | ng/mL | 1.7 | 1.3 – 2.0 | 22 | 17 – 26 | µg/L | 1.7 | 1.3 – 2.0 | 22 | 17 – 26 |
| ltis SR1 (Automated System) (2) | ng/mL | 1.6 | 1.2 – 2.0 | 19 | 14 – 25 | µg/L | 1.6 | 1.2 – 2.0 | 19 | 14 – 25 |
| ckman Coulter ACCESS Hybritech | ng/mL | 2.5 | 2.1 – 2.9 | >20 | | µg/L | 2.5 | 2.1 – 2.9 | >20 | |
| Check EIA (2) | ng/mL | 6.0 | 5.0 – 7.0 | >25 | | µg/L | 6.0 | 5.0 – 7.0 | >25 | |
| Mérieux VIDAS (2) | ng/mL | 2.0 | 1.5 – 2.5 | >10 | | µg/L | 2.0 | 1.5 – 2.5 | >10 | |
| Ag EIA (2) | ng/mL | 1.6 | 1.2 – 2.0 | >10 | | µg/L | 1.6 | 1.2 – 2.0 | >10 | |
| gnostic Products Coat-A-Count IRMA | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| gnostic Products Immulite | ng/mL | 1.7 | 1.5 – 1.9 | 22 | 19 – 24 | µg/L | 1.7 | 1.5 – 1.9 | 22 | 19 – 24 |
| gnostic Products Immulite 2000 | ng/mL | 1.8 | 1.5 – 2.1 | 21 | 16 – 25 | µg/L | 1.8 | 1.5 – 2.1 | 21 | 16 – 25 |
| nunotech IRMA (2) | ng/mL | 1.6 | 1.1 – 2.1 | 20 | 14 – 26 | µg/L | 1.6 | 1.1 – 2.1 | 20 | 14 – 26 |
| che Cobas Core EIA (2) | ng/mL | 1.8 | 1.4 – 2.2 | 21 | 16 – 27 | µg/L | 1.8 | 1.4 – 2.2 | 21 | 16 – 27 |
| che Elecsys | ng/mL | 1.9 | 1.4 – 2.5 | 23 | 16 – 29 | µg/L | 1.9 | 1.4 – 2.5 | 23 | 16 – 29 |
| Magiwel Quantitative (2) | ng/mL | 1.1 | 0.8 – 1.4 | >15 | | µg/L | 1.1 | 0.8 – 1.4 | >15 | |
| llac AutoDELFIA/DELFIA Prostatus Free (2) | ng/mL | 1.6 | 1.3 – 1.9 | 18 | 14 – 22 | µg/L | 1.6 | 1.3 – 1.9 | 18 | 14 – 22 |

## TNOTES // Fussnoten // Notes // Note a pie' pagina // Notas a pie de página // Notas de rodapé // Fotnoter // Fodnoter

dilution should be made prior to running those tests nere the value listed exceeds the highest standard

st kit/instrument has not been cleared by the FDA for s analyte Please refer to 21 §CFR 809 30 for additional formation regarding the regulation of analyte specific agents

A 15-3, CA 72-4, CA 19-9 & CA 125 are trademarks of ujrebio Diagnostics, a division of Fujirebio, Inc , 200 reat Valley Parkway, Malvern, PA 19355

YFRA 21-1 RIA is based on the KS 19 1 and BM 19 21 ntibody system licensed to Fujirebio, Inc , its distributors id licensees, by Roche GmbH

on-spiked analyte No claim is made for performance stability

ata not available at the time of printing Please inquire

he data required to establish the means and ceptable ranges for this assay were not obtained due limited assignment participation If your facility is terested in participating in the Value Assignment rogram for this assay, please contact your local o-Rad Sales or Technical Services Group

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DEUTSCH

or der Durchfuhrung von Tests, bei denen der ngegebene Zielwert die Konzentration des hochsten tandards ubersteigt, ist eine Verdunnung vorzunehmen

eser(s) Test /Gerat hat keine FDA Zulassung fur diesen nalyten Weitere Informationen bezuglich der orschriften fur Reagenzien mit spezifischen Analyten efinden sich in den FDA-Vorschriften 21 CFR §809 30

A 15-3, CA 72-4, CA 19-9 und CA 125 sind /arenzeichen der Fujirebio Diagnostics, einem nternehmensbereich von Fujirebio, Inc., 200 Great Valley arkway, Malvern, Pennsylvania 19355, USA

YFRA 21-1 RIA *basiert auf dem KS 19.1 und BM 19 21* ntikorpersystem, das von Roche GmbH an Fujirebio, Inc nd deren Distributoren und Lizenznehmer lizensiert urde

icht zugesetzter Analyt Es konnen keine Angaben nsichtlich der Leistungsmerkmale oder der Stabilitat emacht werden

aten zum Zeitpunkt des Drucks nicht verfugbar tte nachfragen

ur die Ermittlung der Zielwerte fur diesen Test standen icht genugend Sollwertermittler zur Verfugung eswegen ist die Anzahl der vorliegenden Meßergebnisse icht ausreichend, um sichere Mittelwerte und azugehorige zulassige Bereiche fur diesen

Wenn Ihre Einrichtung interessiert ist, bei künftigen ollwertermittlungen fur diesen Test teilzunehmen, ann bitten wir Sie ihre lokale Bio-Rad Niederlassung der unser Kundendienst-Team zu kontaktieren.

FRANÇAIS

(1) Une dilution doit être effectuée avant de procéder à ces essais si la valeur indiquée dépasse la valeur étalon la plus élevée

(2) Ce kit/instrument d'analyse n'a pas été autorisé par la FDA pour cet analyte Se reporter à 21 §CFR 809.30 pour des renseignements complémentaires sur la réglementation des réactifs d'analyses spécifiques

(3) CA 15-3, CA 72-4, CA 19-9 et CA 125 sont des marques commerciales de Fujirebio Diagnostics, une division de Fujirebio, Inc , 200 Great Valley Parkway, Malvern, PA 19355, USA

(4) Le CYFRA 21-1 RIA est basé sur le système d'anticorps KS 19.1 et BM 19 21 licencié auprès de Fujirebio, Inc., ses distributeurs et ses concédants par Roche GmbH

(5) Le produit n'est pas enrichi de cet analyte Aucune revendication n'est faite concernant les performances et la stabilité

Δ Données non disponibles à la date d'impression Prière de se renseigner

§ Le nombre de données n'a pas été suffisant pour définir la moyenne et les limites acceptables pour ce dosage en raison du manque de laboratoires pour *établir ces valeurs. Si votre laboratoire souhaite* participer à l'élaboration de ces valeurs, veuillez contacter votre correspondant Bio-Rad

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ITALIANO

(1) Procedere alla diluizione prima dell'esecuzione dei test i cui i valori elencati superano la concentrazione dello standard più alto

(2) Il kit/strumento non è stato approvato dalla FDA per *questo analita Per ulteriori informazioni sulla normativa* riguardante i reattivi specifici per l'analita fare riferimento a 21 §CFR 809 30

(3) CA 15-3, CA 72-4, CA 19-9 e CA 125 *sono marchi* registrati della Fujirebio Diagnostics, una divisione Fujirebio, Inc , 200 Great Valley Parkway, Malvern, PA 19355, Stati Uniti.

(4) CYFRA 21-1 RIA si basa sul sistema anticorpale KS 19 1 e BM 19 21 dato in licenza a Fujirebio, Inc., ai suoi distributori e concessionari, dalla Roche GmbH

(5) Analita non aggiunto Non vengono forniti dati sulle prestazioni, né dati di stabilita

Δ Dati non disponibili al momento della stampa Richiedere informazioni

§ A causa della bassa o nulla partecipazione nell'assegnazione valori, la media e gli intervalli di riferimento per questo dosaggio non sono stati definiti Contattare gli uffici locali per maggiori chiarimenti

ESPAÑOL

(1) Debe efectuarse una dilución antes de llevar a cabo las pruebas cuando el valor indicado excede el estándar más alto

(2) El kit/instrumento de prueba no ha sido homologado por la FDA para este analito Consulte 21 CFR §809 30 para obtener más información sobre la regulación de reactivos específicos para el analito

(3) CA 15-3, CA 72-4, CA 19-9 y CA 125 son marcas comerciales de Fujirebio Diagnostics, división de Fujirebio, Inc., 200 Great Valley Parkway, Malvern, PA 19355 (Estados Unidos)

(4) CYFRA 21-1 RIA se basa en el sistema de anticuerpos KS 19.1 y BM 19 21, cuya licencia Roche GmbH otorga a Fujirebio, Inc, sus distribuidores y licenciatarios.

(5) Analito no añadido al control No se garantiza el comportamiento ni la estabilidad.

Δ No se disponía de información en el momento en que se imprimió este prospecto. Consulte cualquier duda

§ Debido a la baja o nula participación en la asignación de valores, *no se ha podido establecer los valores medios* y rangos aceptables de este ensayo Si su centro de trabajo está interesado en participar en la valoración de este ensayo, por favor contacte con su oficina local de Bio-Rad

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PORTUGUÊS

(1) Deve ser efectuada uma diluição antes de se efectuarem as análises nas quais o valor listado ultrapassa o padrão *mais elevado*

(2) O dispositivo de teste/instrumento ainda não foi autorizado pela FDA relativamente a este analito. Para obter mais informações sobre a regulamentação relativa a reagentes específicos de analitos, consulte a secção 21 §CFR 809 30 do codigo de regulamentos federais

(3) CA 15-3, CA 72-4, CA 19-9 & CA 125 são marcas comerciais da Fujirebio Diagnostics, uma divisão da Fujirebio, Inc , 200 Great Valley Parkway, Malvern, PA 19355

(4) O CYFRA 21-1 RIA baseia-se no sistema anticorpos KS 19 1 e BM 19.21 licenciado à Fujirebio, Inc , seus distribuidores e licenciados pela Roche GmbH

(5) Analito sem picos Não foi feita qualquer afirmação em relação ao desempenho ou à estabilidade

Δ Os dados não se encontravam disponíveis na altura da impressão do folheto Por favor, efectue os devidos inquéritos.

§ Os dados necessários para a obtenção da média e do intervalo de referência para este analito não foram obtidos dada a limitada participação na atribuição de valores Se estiver interessado em participar no nosso *Programa de Atribuição de Valores, por favor entre em* contacto com o seu representante local

SVENSKA

(1) Produkten skall spädas innan tester vars angivna varden ligger över hogsta standardvärde utfors

(2) Testkittet/instrumentet har inte godkants av FDA for denna analyt Se punkt 21 i CFR (Code of Federal Regulations) § 809 30 for ytterligare information om bestammelser angående analytspecifika reagenser

(3) CA 15-3, CA 72-4, CA 19-9 & CA 125 är varumarken som tillhor Fujirebio Diagnostics, en avdelning av Fujirebio, Inc , 200 Great Valley Parkway, Malvern, PA 19355, USA

(4) CYFRA 21-1 RIA är baserat på antikroppssystemet KS 19 1 och BM 19 21 som anvands av Fujirebio, Inc , dess distributorer och licensinnehavare på licens från Roche GmbH

(5) Ej invagd analyt Inga utfastelser avseende prestanda eller hållbarhet utfärdas.

Δ Data finns inte tillgängliga vid tidpunkten for tryckning Var god kontakta Bio-Rad Laboratories

§ Nodvandig data for att faststalla medelvarden och acceptabla matområden for denna analys kunde inte insamlas på grund av ett alltför begransat deltagarantal vid tilldelning av varden Om din institution/ditt laboratorium onskar deltaga i *programmet for tilldelning av varden (Value* Assignment Program) for denna analys, var god kontakta Bio-Rads forsaljningsavdelning eller tekniska serviceavdelning

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DANSK

(1) *Der bør laves en fortynding inden de tests, hvor den* anførte værdi er højere end den højeste standard, udføres

(2) Testkit/instrument er ikke godkendt af FDA til denne analyt *Der henvises til 21 §CFR 809 30 for yderligere* oplysninger om regulativer vedr. analytspecifikke reagenser.

(3) CA 15-3, CA 72-4, CA 19-9 og CA 125 *er varemærker*, der tilhører Fujirebio Diagnostics, en division af Fujirebio, Inc , 200 Great Valley Parkway, Malvern, PA 19355, USA

(4) CYFRA 21-1 RIA er baseret på KS 19 1 og BM 19 21 antistofsystem, hvortil Fujirebio, Inc , deres distributører og licenshavere af Roche GmbH har fået licensret

(5) Analyt uden tilsætning. Der hævdes intet om præstation og holdbarhed

Δ Ingen tilgængelige data da denne indlægsseddel gik i trykken Oplysning fås ved henvendelse

§ Pga for lille tilslutning til vores "Value Assignment Program" har det desværre ikke været muligt at have middelværdien og standart variationenværdien med på denne analyse Skulle du/i være interesseret i at deltage i dette program for denne analyse, så kontakt venligst det lokale Bio-Rad

# TABLE WITH ASSIGNED VALUES

The ranges provided are calculated using Annex 1a column 7 of the German Medical Association Directive on Quality Assurance of Quantitative Laboratory Tests for Medical Purposes from 24 August 2001, published in the "Deutsche Ärzteblatt" Vol. 98 / No. 42 / 19 October 2001 / Page A 2747 and revised on 22 March 2002 by the German Medical Association Board in Annex 1 a-d of the above mentioned Guideline, published in the "Deutsche Ärzteblatt" Vol. 99 / No. 17 / 26 April 2002 / Page A 1187

# ZIELWERTTABELLE

Die angegebenen zulässigen Bereiche wurden nach der Anlage 1a, Spalte 7 der Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen vom 24. August 2001, veröffentlicht im Deutschen Ärzteblatt / Jg. 98 / Heft 42 / 19. Oktober 2001 / Seite A 2747 bzw. den am 22. März 2002 im Vorstand beschlossenen Änderungen der Anlagen 1 a-d der o.g. Richtlinie, veröffentlicht im Deutschen Ärzteblatt / Jg. 99 / Heft 17 / 26 April 2002 / Seite A 1187 berechnet.

| GERMAN RANGES | | RILIBÄK - BEREICHE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | LEVEL 1 – 44111 | | LEVEL 2 – 44112[1] | | | LEVEL 1 – 44111 | | LEVEL 2 – 44112[1] | |
| | UNITS | MEAN | RANGE | MEAN | RANGE | SI | MEAN | RANGE | MEAN | RANGE |
| **AFP (ALPHA-FETOPROTEIN)** | | | | | | | | | | |
| Abbott Architect | ng/mL | 28 | 22 – 35 | 120 | 92 – 149 | µg/L | 28 | 22 – 35 | 120 | 92 – 149 |
| Abbott AxSYM | ng/mL | 24 | 18 – 30 | 115 | 87 – 143 | µg/L | 24 | 18 – 30 | 115 | 87 – 143 |
| Abbott IMx | ng/mL | 20 | 15 – 24 | 103 | 79 – 128 | µg/L | 20 | 15 – 24 | 103 | 79 – 128 |
| Adaltis BRIDGE (2) | IU/mL | 24 | 18 – 30 | 118 | 89 – 146 | kIU/L | 24 | 18 – 30 | 118 | 89 – 146 |
| Adaltis SR1 (Automated System) (2) | IU/mL | 21 | 16 – 26 | 88 | 67 – 109 | kIU/L | 21 | 16 – 26 | 88 | 67 – 109 |
| Bayer ACS.180 | ng/mL | 28 | 21 – 34 | 110 | 84 – 137 | µg/L | 28 | 21 – 34 | 110 | 84 – 137 |
| Bayer Advia Centaur | ng/mL | 27 | 20 – 33 | 110 | 84 – 137 | µg/L | 27 | 20 – 33 | 110 | 84 – 137 |
| Bayer Immuno I | ng/mL | 23 | 17 – 29 | 91 | 69 – 113 | µg/L | 23 | 17 – 29 | 91 | 69 – 113 |
| Beckman Coulter ACCESS (WHO 1st IS 72/225) | ng/mL | 25 | 19 – 31 | 107 | 81 – 133 | µg/L | 25 | 19 – 31 | 107 | 81 – 133 |
| BioCheck EIA (WHO 1st IS 72/225) (2) | ng/mL | 20 | 15 – 25 | 91 | 69 – 113 | µg/L | 20 | 15 – 25 | 91 | 69 – 113 |
| bioMérieux VIDAS (2) | IU/mL | 20 | 15 – 25 | 90 | 68 – 112 | kIU/L | 20 | 15 – 25 | 90 | 68 – 112 |
| Byk-Sangtec IRMA RIA-mat 280 (1st IS 72/225) (2) | IU/mL | 21 | 16 – 26 | 91 | 69 – 113 | kIU/L | 21 | 16 – 26 | 91 | 69 – 113 |
| Byk-Sangtec LIA-mat S300 (1st IS 72/225) (2) | IU/mL | 21 | 16 – 26 | 92 | 70 – 114 | kIU/L | 21 | 16 – 26 | 92 | 70 – 114 |
| Byk-Sangtec LIAISON (1st IS 72/225) (2) | IU/mL | 20 | 15 – 25 | 86 | 65 – 106 | kIU/L | 20 | 15 – 25 | 86 | 65 – 106 |
| CanAg EIA (2) | ng/mL | 26 | 20 – 32 | 118 | 90 – 146 | µg/L | 26 | 20 – 32 | 118 | 90 – 146 |
| CIS RIA gnost (WHO 72/225) | IU/mL | Δ | | Δ | | kIU/L | Δ | | Δ | |
| Diagnostic Products Coat-A-Count IRMA (2) | IU/mL | 20 | 15 – 24 | 84 | 64 – 104 | kIU/L | 20 | 15 – 24 | 84 | 64 – 104 |
| Diagnostic Products Immulite | IU/mL | 18 | 14 – 22 | 78 | 59 – 96 | kIU/L | 18 | 14 – 22 | 78 | 59 – 96 |
| Diagnostic Products Immulite 2000 | IU/mL | 18 | 13 – 22 | 79 | 60 – 97 | kIU/L | 18 | 13 – 22 | 79 | 60 – 97 |
| Diagnostic Products TC Double Antibody IRMA | IU/mL | 17 | 13 – 21 | 94 | 71 – 116 | kIU/L | 17 | 13 – 21 | 94 | 71 – 116 |
| DiaSorin M-K-S (WHO 72/225) (2) | ng/mL | 23 | 18 – 29 | 98 | 75 – 122 | µg/L | 23 | 18 – 29 | 98 | 75 – 122 |
| Immunotech IRMA (WHO 72/225) (2) | IU/mL | 22 | 17 – 27 | 99 | 75 – 123 | kIU/L | 22 | 17 – 27 | 99 | 75 – 123 |
| Ortho Clinical Diagnostic Vitros ECi (1st IRP 72/225) | IU/mL | 19 | 14 – 23 | 75 | 57 – 93 | kIU/L | 19 | 14 – 23 | 75 | 57 – 93 |
| Radim BRIO (WHO 72/225) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Radim IRMA CT (WHO 72/225) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Roche Cobas Core EIA (2) | IU/mL | 23 | 17 – 28 | 103 | 78 – 128 | kIU/L | 23 | 17 – 28 | 103 | 78 – 128 |
| Roche Elecsys | IU/mL | 20 | 15 – 24 | 90 | 68 – 112 | kIU/L | 20 | 15 – 24 | 90 | 68 – 112 |
| TOSOH AIA-PACK IEMA (IS 72/225) | ng/mL | 24 | 18 – 29 | 108 | 82 – 134 | µg/L | 24 | 18 – 29 | 108 | 82 – 134 |
| UBI Magiwel Quantitative (WHO 72/225) (2) | IU/mL | 20 | 15 – 24 | 70 | 53 – 86 | kIU/L | 20 | 15 – 24 | 70 | 53 – 86 |
| **ALDOSTERONE** | | | | | | | | | | |
| Diagnostic Products Coat-A-Count | pg/mL | 215 | 118 – 312 | 1145 | 630 – >1660 | pmol/L | 596 | 328 – 864 | 3172 | 1744 – >4599 |
| DiaSorin ALDOCTK-2 (2) | pg/mL | 248 | 136 – 360 | >1000 | | pmol/L | 687 | 378 – 996 | >2770 | |
| **FERRITIN** | | | | | | | | | | |
| Abbott Architect | ng/mL | 45 | 34 – 56 | 356 | 271 – 441 | µg/L | 45 | 34 – 56 | 356 | 271 – 441 |
| Adaltis SR1 (Automated System) (2) | ng/mL | 37 | 28 – 46 | 272 | 206 – 337 | µg/L | 37 | 28 – 46 | 272 | 206 – 337 |
| Bayer ACS 180 | ng/mL | 46 | 35 – 57 | 323 | 246 – 401 | µg/L | 46 | 35 – 57 | 323 | 246 – 401 |
| Bayer Advia Centaur | ng/mL | 47 | 36 – 58 | 334 | 254 – 414 | µg/L | 47 | 36 – 58 | 334 | 254 – 414 |
| Bayer Immuno 1 | ng/mL | 41 | 31 – 51 | 298 | 226 – 369 | µg/L | 41 | 31 – 51 | 298 | 226 – 369 |
| BioCheck EIA | ng/mL | 44 | 33 – 55 | 269 | 204 – 334 | µg/L | 44 | 33 – 55 | 269 | 204 – 334 |
| bioMérieux VIDAS | ng/mL | 52 | 40 – 64 | 357 | 271 – 443 | µg/L | 52 | 40 – 64 | 357 | 271 – 443 |
| Bio-Rad Quantimune IRMA | ng/mL | 45 | 35 – 56 | 367 | 279 – 455 | µg/L | 45 | 35 – 56 | 367 | 279 – 455 |
| Byk-Sangtec IRMA-mat/ RIA-mat 280 (2nd IS 80/578) (2) | ng/mL | 49 | 38 – 61 | 335 | 255 – 415 | µg/L | 49 | 38 – 61 | 335 | 255 – 415 |
| Byk-Sangtec LIAISON (2nd IS 80/578) (2) | ng/mL | 47 | 36 – 59 | 382 | 290 – 474 | µg/L | 47 | 36 – 59 | 382 | 290 – 474 |
| Diagnostic Products Coat-A-Count IRMA | ng/mL | 47 | 36 – 58 | 270 | 205 – 335 | µg/L | 47 | 36 – 58 | 270 | 205 – 335 |
| Diagnostic Products Immulite | ng/mL | 49 | 37 – 61 | 301 | 229 – 373 | µg/L | 49 | 37 – 61 | 301 | 229 – 373 |
| Diagnostic Products Immulite 2000 | ng/mL | 53 | 40 – 66 | 323 | 245 – 401 | µg/L | 53 | 40 – 66 | 323 | 245 – 401 |
| Immunotech IRMA (2) | ng/mL | 44 | 34 – 55 | 261 | 198 – 324 | µg/L | 44 | 34 – 55 | 261 | 198 – 324 |
| Ortho Clinical Diagnostics Vitros ECi | ng/mL | 45 | 34 – 56 | 243 | 185 – 301 | µg/L | 45 | 34 – 56 | 243 | 185 – 301 |
| RADIM BRIO (WHO/MRC 80/602) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| RADIM IRMA CT (WHO/MRC 80/602) (2) | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| Roche Cobas Core EIA (2) | ng/mL | 46 | 35 – 57 | 402 | 306 – 498 | µg/L | 46 | 35 – 57 | 402 | 306 – 498 |
| Roche Elecsys | ng/mL | 52 | 39 – 64 | 329 | 250 – 408 | µg/L | 52 | 39 – 64 | 329 | 250 – 408 |
| TOSOH AIA-PACK IEMA (1st IS 80/602) | ng/mL | 42 | 32 – 52 | 283 | 215 – 351 | µg/L | 42 | 32 – 52 | 283 | 215 – 351 |
| UBI Magiwel Quantitative (NIBSC 94/572) | ng/mL | 32 | 24 – 40 | 265 | 201 – 328 | µg/L | 32 | 24 – 40 | 265 | 201 – 328 |
| **hCG (HUMAN CHORIONIC GONADOTROPIN)** | | | | | | | | | | |
| Abbott IMx | mIU/mL | 11.0 | 7.0 – 15.0 | 106 | 68 – 144 | IU/L | 11.0 | 7.0 – 15.0 | 106 | 68 – 144 |
| Adaltis SR1 (Automated System) | mIU/mL | 12.7 | 8.1 – 17.3 | 127 | 81 – 173 | IU/L | 12.7 | 8.1 – 17.3 | 127 | 81 – 173 |
| Adaltis Maiaclone | mIU/mL | 16.4 | 10.5 – 22.3 | 152 | 97 – 207 | IU/L | 16.4 | 10.5 – 22.3 | 152 | 97 – 207 |
| Bayer Advia Centaur | mIU/mL | 10.0 | 6.4 – 13.6 | 107 | 68 – 145 | IU/L | 10.0 | 6.4 – 13.6 | 107 | 68 – 145 |
| Bayer Immuno 1 | mIU/mL | 13.1 | 8.4 – 17.9 | 128 | 82 – 174 | IU/L | 13.1 | 8.4 – 17.9 | 128 | 82 – 174 |
| bioMérieux VIDAS (1st IRP 75/537) | mIU/mL | 12.0 | 7.7 – 16.3 | 132 | 84 – 180 | IU/L | 12.0 | 7.7 – 16.3 | 132 | 84 – 180 |
| Byk Sangtec LIAISON (1st IRP 75/537) (2) | mIU/mL | 6.3 | 4.0 – 8.6 | 77 | 49 – 105 | IU/L | 6.3 | 4.0 – 8.6 | 77 | 49 – 105 |

| ERMAN RANGES | | RILIBÄK - BEREICHE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | LEVEL 1 – 44111 | | LEVEL 2 – 44112[1] | | | LEVEL 1 – 44111 | | LEVEL 2 – 44112[1] | |
| | UNITS | MEAN | RANGE | MEAN | RANGE | SI | MEAN | RANGE | MEAN | RANGE |
| **G (HUMAN CHORIONIC GONADOTROPIN) (continued)** | | | | | | | | | | |
| iagnostic Products Immulite Turbo | mIU/mL | 14.2 | 9.1 – 19 3 | 152 | 97 – 207 | IU/L | 14 2 | 9.1 – 19.3 | 152 | 97 – 207 |
| iagnostic Products Immulite 2000 | mIU/mL | 14.7 | 9.4 – 20.0 | 160 | 102 – 218 | IU/L | 14 7 | 9.4 – 20 0 | 160 | 102 – 218 |
| mmunotech IRMA (2) | mIU/mL | 9.0 | 5.8 – 12 2 | 87 | 56 – 118 | IU/L | 9.0 | 5.8 – 12.2 | 87 | 56 – 118 |
| OSOH AIA–PACK IEMA (3rd IS 75/537) | mIU/mL | 14.3 | 9 2 – 19 4 | 145 | 93 – 197 | IU/L | 14 3 | 9.2 – 19.4 | 145 | 93 – 197 |
| BI Magiwel Quantitative (WHO 3rd IS 75/537) | mIU/mL | 12 5 | 8 0 – 17 0 | 126 | 80 – 171 | IU/L | 12 5 | 8.0 – 17.0 | 126 | 80 – 171 |
| **G–BETA SUBUNIT** | | | | | | | | | | |
| bbott Architect | mIU/mL | 8.4 | 5.4 – 11.4 | 83 | 53 – 114 | IU/L | 8.4 | 5 4 – 11 4 | 83 | 53 – 114 |
| bbott AxSYM | mIU/mL | 13.0 | 8 3 – 17.7 | 139 | 89 – 189 | IU/L | 13.0 | 8.3 – 17 7 | 139 | 89 – 189 |
| bbott IMx | mIU/mL | 12.2 | 7.8 – 16 6 | 136 | 87 – 185 | IU/L | 12.2 | 7 8 – 16 6 | 136 | 87 – 185 |
| ayer ACS:180 | mIU/mL | 11 3 | 7.2 – 15.3 | 121 | 77 – 165 | IU/L | 11.3 | 7 2 – 15.3 | 121 | 77 – 165 |
| ayer Advia Centaur | mIU/mL | 11 1 | 7 1 – 15 1 | 120 | 77 – 163 | IU/L | 11.1 | 7.1 – 15 1 | 120 | 77 – 163 |
| rtho Clinical Diagnostics Vitros ECi (3rd IS 75/537) | mIU/mL | 13.7 | 8 8 – 18.6 | 143 | 92 – 194 | IU/L | 13.7 | 8 8 – 18.6 | 143 | 92 – 194 |
| ADIM BRIO (WHO 61/6) (2) | mIU/mL | Δ | | Δ | | IU/L | Δ | | Δ | |
| ADIM IRMA CT (WHO 75/537) (2) | mIU/mL | Δ | | Δ | | IU/L | Δ | | Δ | |
| oche Cobas Core EIA II (2) | mIU/mL | 9.6 | 6.1 – 13.0 | 94 | 60 – 127 | IU/L | 9.6 | 6 1 – 13.0 | 94 | 60 – 127 |
| OSOH AIA–PACK IEMA (3rd IS 75/537) | mIU/mL | 14 5 | 9.3 – 19.7 | 143 | 92 – 194 | IU/L | 14.5 | 9 3 – 19.7 | 143 | 92 – 194 |
| **(PROSTATE SPECIFIC ANTIGEN)** | | | | | | | | | | |
| bott Architect | ng/mL | 1.8 | 1.3 – 2.4 | 22 | 15 – 28 | µg/L | 1 8 | 1.3 – 2.4 | 22 | 15 – 28 |
| bbott AxSYM (MEIA) (Mono/Mono Kit # 3C19) | ng/mL | 1.7 | 1.2 – 2.2 | 21 | 15 – 27 | µg/L | 1 7 | 1 2 – 2.2 | 21 | 15 – 27 |
| bbott AxSYM (MEIA) (Mono/Poly Kit # 7A49) | ng/mL | 3.8 | 2.6 – 4 9 | 46 | 32 – 59 | µg/L | 3.8 | 2 6 – 4.9 | 46 | 32 – 59 |
| bbott IMx | ng/mL | 3.7 | 2.6 – 4.8 | 47 | 33 – 61 | µg/L | 3 7 | 2.6 – 4.8 | 47 | 33 – 61 |
| altis SR1 (Automated System) (2) | ng/mL | 1.7 | 1.2 – 2.1 | 29 | 20 – 37 | µg/L | 1 7 | 1.2 – 2.1 | 29 | 20 – 37 |
| altis Maiaclone (2) | ng/mL | 2.3 | 1.6 – 2.9 | 26 | 18 – 34 | µg/L | 2.3 | 1.6 – 2.9 | 26 | 18 – 34 |
| yer ACS.180 (Equimolar) | ng/mL | 2.2 | 1.5 – 2.8 | 24 | 17 – 31 | µg/L | 2 2 | 1 5 – 2.8 | 24 | 17 – 31 |
| yer Advia Centaur (Equimolar) | ng/mL | 1.9 | 1.3 – 2.4 | 21 | 15 – 28 | µg/L | 1 9 | 1 3 – 2.4 | 21 | 15 – 28 |
| yer Immuno I | ng/mL | 2.1 | 1.5 – 2.7 | 29 | 20 – 37 | µg/L | 2.1 | 1.5 – 2 7 | 29 | 20 – 37 |
| ckman Coulter ACCESS Hybritech | ng/mL | 2.9 | 2 0 – 3.7 | 34 | 24 – 44 | µg/L | 2.9 | 2.0 – 3 7 | 34 | 24 – 44 |
| Check EIA (2) | ng/mL | 5.0 | 3.5 – 6.5 | 69 | 48 – 90 | µg/L | 5 0 | 3.5 – 6.5 | 69 | 48 – 90 |
| Mérieux VIDAS | ng/mL | 2.6 | 1.8 – 3.4 | 29 | 20 – 38 | µg/L | 2 6 | 1.8 – 3 4 | 29 | 20 – 38 |
| k–Sangtec IRMA–mat/RIA–mat 280 (2) | ng/mL | 2.1 | 1.5 – 2.7 | 27 | 19 – 34 | µg/L | 2.1 | 1 5 – 2.7 | 27 | 19 – 34 |
| k–Sangtec LIA–mat/LIA–mat S300 (2) | ng/mL | 2 7 | 1.9 – 3.5 | 33 | 23 – 43 | µg/L | 2.7 | 1 9 – 3.5 | 33 | 23 – 43 |
| k–Sangtec LIAISON (2) | ng/mL | 2.1 | 1.5 – 2.7 | 27 | 19 – 35 | µg/L | 2 1 | 1.5 – 2 7 | 27 | 19 – 35 |
| nAg EIA (2) | ng/mL | 2.2 | 1.5 – 2.9 | 27 | 19 – 35 | µg/L | 2.2 | 1 5 – 2 9 | 27 | 19 – 35 |
| S RIA CT | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| de Behring Dimension (TPSA) | ng/mL | 1 8 | 1 2 – 2.3 | 22 | 15 – 29 | µg/L | 1.8 | 1 2 – 2 3 | 22 | 15 – 29 |
| gnostic Products Coat–A–Count IRMA | ng/mL | 1.8 | <1 3 – 2.3 | 24 | 17 – 31 | µg/L | 1.8 | <1.3 – 2.3 | 24 | 17 – 31 |
| gnostic Products Immulite | ng/mL | 2.9 | 2.0 – 3.8 | 32 | 22 – 41 | µg/L | 2 9 | 2 0 – 3 8 | 32 | 22 – 41 |
| gnostic Products Immulite 3rd Gen | ng/mL | 2.2 | 1.5 – 2 9 | >20 | | µg/L | 2 2 | 1 5 – 2.9 | >20 | |
| gnostic Products Immulite 2000 | ng/mL | 2.8 | 1.9 – 3.6 | 33 | 23 – 43 | µg/L | 2 8 | 1 9 – 3 6 | 33 | 23 – 43 |
| gnostic Products Immulite 2000 3rd Gen. | ng/mL | 2 3 | 1.6 – 2.9 | >20 | | µg/L | 2.3 | 1.6 – 2 9 | >20 | |
| nunotech IRMA (2) | ng/mL | 1 8 | 1.3 – 2 3 | 22 | 15 – 28 | µg/L | 1 8 | 1.3 – 2 3 | 22 | 15 – 28 |
| ho Clinical Diagnostics Vitros ECi | ng/mL | 2 1 | 1.5 – 2.7 | 22 | 15 – 29 | µg/L | 2.1 | 1 5 – 2 7 | 22 | 15 – 29 |
| che Cobas Core EIA II (2) | ng/mL | 2.2 | 1.6 – 2 9 | 29 | 20 – 38 | µg/L | 2 2 | 1 6 – 2 9 | 29 | 20 – 38 |
| che Elecsys | ng/mL | 2 6 | 1.8 – 3.4 | 31 | 22 – 40 | µg/L | 2 6 | 1 8 – 3 4 | 31 | 22 – 40 |
| SOH AIA–PACK IEMA | ng/mL | 2.4 | 1.7 – 3.1 | 28 | 20 – 36 | µg/L | 2.4 | 1 7 – 3.1 | 28 | 20 – 36 |
| Magiwe' Quantitative (2) | ng/mL | 2 3 | 1.6 – 3 0 | 30 | 21 – 39 | µg/L | 2.3 | 1.6 – 3 0 | 30 | 21 – 39 |
| lac AutoDELFIA/DELFIA Prostatus EQM (2) | ng/mL | 1 9 | 1.3 – 2.5 | 22 | 15 – 29 | µg/L | 1.9 | 1.3 – 2 5 | 22 | 15 – 29 |
| lac AutoDELFIA/DELFIA Prostatus Total (2) | ng/mL | 1 9 | 1.3 – 2 5 | 21 | 15 – 27 | µg/L | 1 9 | 1 3 – 2 5 | 21 | 15 – 27 |
| **PSA** | | | | | | | | | | |
| bott Architect | ng/mL | 1 9 | 1.4 – 2.5 | 24 | 17 – 32 | µg/L | 1.9 | 1 4 – 2 5 | 24 | 17 – 32 |
| bott AxSYM (2) | ng/mL | 1.7 | 1.2 – 2 2 | 22 | 15 – 28 | µg/L | 1.7 | 1 2 – 2 2 | 22 | 15 – 28 |
| ltis SR1 (Automated System) (2) | ng/mL | 1 6 | 1.1 – 2.0 | 19 | 13 – 25 | µg/L | 1 6 | 1 1 – 2.0 | 19 | 13 – 25 |
| kman Coulter ACCESS Hybritech | ng/mL | 2.5 | 1.7 – 3.2 | >20 | | µg/L | 2.5 | 1.7 – 3 2 | >20 | |
| Check EIA (2) | ng/mL | 6 0 | 4 2 – 7.8 | >25 | | µg/L | 6.0 | 4.2 – 7.8 | >25 | |
| Mérieux VIDAS (2) | ng/mL | 2 0 | 1.4 – 2.6 | >10 | | µg/L | 2.0 | 1 4 – 2.6 | >10 | |
| Ag EIA (2) | ng/mL | 1.6 | 1.1 – 2.1 | >10 | | µg/L | 1 6 | 1.1 – 2 1 | >10 | |
| gnostic Products Coat–A–Count IRMA | ng/mL | Δ | | Δ | | µg/L | Δ | | Δ | |
| gnostic Products Immulite | ng/mL | 1.7 | 1.2 – 2.2 | 22 | 15 – 28 | µg/L | 1 7 | 1.2 – 2.2 | 22 | 15 – 28 |
| gnostic Products Immulite 2000 | ng/mL | 1 8 | 1.3 – 2.3 | 21 | 14 – 27 | µg/L | 1.8 | 1.3 – 2.3 | 21 | 14 – 27 |
| nunotech IRMA (2) | ng/mL | 1.6 | 1.1 – 2.1 | 20 | 14 – 26 | µg/L | 1.6 | 1 1 – 2.1 | 20 | 14 – 26 |
| he Cobas Core EIA (2) | ng/mL | 1.8 | 1.3 – 2.3 | 21 | 15 – 27 | µg/L | 1.8 | 1 3 – 2 3 | 21 | 15 – 27 |
| he Elecsys | ng/mL | 1.9 | 1.3 – 2.5 | 23 | 16 – 29 | µg/L | 1 9 | 1.3 – 2 5 | 23 | 16 – 29 |
| Magiwel Quantitative (2) | ng/mL | 1 1 | 0.8 – 1.4 | >15 | | µg/L | 1.1 | 0 8 – 1.4 | >15 | |
| ac AutoDELFIA/DELFIA Prostatus Free (2) | ng/mL | 1.6 | 1.1 – 2.1 | 18 | 13 – 23 | µg/L | 1 6 | 1.1 – 2 1 | 18 | 13 – 23 |

## TNOTES

lution should be made prior to running those tests where the value listed exceeds the highest standard.
t kit/instrument has not been cleared by the FDA for this analyte. Please refer to 21 §CFR 809 30 for
itional information regarding the regulation of analyte specific reagents
a not available at the time of printing. Please inquire

## FUSSNOTEN

(1) Vor der Durchfuhrung von Tests, bei denen der angegebene Zielwert die Konzentration des hochsten Standards ubersteigt, ist eine Verdunnung vorzunehmen.

(2) Dieser(s) Test /Gerät hat keine FDA Zulassung fur diesen Analyten Weitere Informationen bezüglich der Vorschriften fur Reagenzien mit spezifischen Analyten befinden sich in den FDA-Vorschriften 21 CFR §809 30

Δ Daten zum Zeitpunkt des Drucks nicht verfugbar. Bitte nachfragen

BIO-RAD

580

# Lyphochek®

2409

## Tumor Marker Control

A human serum assayed tumor marker control
Tumormarker-Kontrolle (Humanserum), mit Zielwertangaben
Contrôle titré de sérum humain pour marqueurs tumoraux
Siero di controllo umano dosato per marcatori tumorali
Suero control humano valorado para marcadores tumorales
Um soro humano ensaiado para controlo dos marcadores tumorais.
En analyserad tumormarkorkontroll framställd av humant serum.
En analyseret human serum tumormarkerkontrol

## Bilevel

6 x 2 mL

CE 0197 | IVD For In Vitro Diagnostic Use | Consult Instructions for Use | 2°C – 8°C | LOT 44110 | EXP 2005-11-30

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