This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

The assigned 510(k) Number is: BK241075

1. Date Prepared

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2. Applicant Information

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3. Regulatory Information

Trade Name	Atellica® IM HIV Ag/Ab Combo (CHIV)
Common Name	Test, HIV Detection
Classification Name	Human immunodeficiency virus (HIV) serological diagnostic and/or supplemental test
FDA Classification	Class II
Review Panel	Microbiology
Product Code	MZF
Regulation Number	21 CFR 866.3956

4. Predicate Device Information

Predicate Device Name: ADVIA Centaur® HIV Ag/Ab Combo (CHIV) assay

PMA Number: BP140103

5. Intended Use / Indications for Use

The Atellica® IM HIV Ag/Ab Combo (CHIV) assay is for *in vitro* diagnostic use in the simultaneous qualitative detection of human immunodeficiency virus p24 antigen and antibodies to human immunodeficiency viruses type 1 (including group “O”) and type 2, in

serum and plasma (potassium EDTA, lithium heparin, sodium heparin) using the Atellica® CI Analyzer. The Atellica IM CHIV assay is intended to be used as an aid in the diagnosis of HIV infection in pediatric and adult populations, including pregnant women.

The Atellica IM CHIV assay is not intended for the screening of donors of blood and blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps). Although the effectiveness of the assay for screening blood or plasma donors has not been established, the assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening tests are unavailable, or if their use is impractical.

A reactive result using the Atellica IM CHIV assay does not distinguish HIV-1 p24 antigen, HIV-1 antibody, HIV-2 antibody, and HIV-1 group O antibody.

6. Special Conditions for Use Statement

For Prescription Use

7. Device Description

Component	Volume	Ingredients
Atellica IM CHIV ReadyPack primary reagent pack (included in assay kit)		
Lite Reagent	5.0 mL/pack	Recombinant HIV antigens (~0.12 µg/mL) and mouse monoclonal anti-HIV antibody (~0.004 µg/mL) labeled with acridinium ester in buffer; bovine serum albumin; mouse IgG; goat serum; surfactant; preservatives
Solid Phase	10.0 mL/pack	Streptavidin-coated paramagnetic microparticles preformed with biotinylated HIV antigens (~1.5 µg/mL) and biotinylated mouse monoclonal anti-HIV antibodies (~4.5 µg/mL) in buffer; bovine serum albumin; mouse IgG; surfactant; preservatives
Ancillary Lite Reagent	5.0 mL/pack	Recombinant HIV antigens (~0.23 µg/mL) and mouse monoclonal anti-HIV antibody (~1.5 µg/mL) labeled with acridinium ester in buffer; bovine serum albumin; mouse IgG; goat serum; surfactant; preservatives
Atellica IM CHIV CAL (included in assay kit)		
CHIV CAL L	2.0 mL/vial	Heat-inactivated goat serum; sodium azide (< 0.1%); preservatives
CHIV CAL H	2.0 mL/vial	Processed* human plasma negative for antibodies to HIV and spiked with antibodies to HIV-1; sodium azide (< 0.1%); preservatives **Processed plasma is defibrinated and filtered plasma.*

8. Comparison of Technological Characteristics with the Predicate Device

The following tables describe the comparison between the Atellica IM HIV Ag/Ab Combo (CHIV) assay (Candidate Device), and the ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay (BP140103 - Predicate Device) and similarities and differences between Atellica CI Analyzer and ADVIA Centaur XP system.

Item	**Candidate Device** **Atellica® IM HIV Ag/Ab Combo (CHIV) assay (on Atellica CI Analyzer)**	**Predicate Device ADVIA Centaur® HIV Ag/Ab Combo (CHIV) assay (on ADVIA Centaur XP system; BP140103)**
Intended Use	The Atellica® IM HIV Ag/Ab Combo (CHIV) assay is for *in vitro* diagnostic use in the simultaneous qualitative detection of human immunodeficiency virus p24 antigen and antibodies to human immunodeficiency viruses type 1 (including group “O”) and type 2, in serum and plasma (potassium EDTA, lithium heparin, sodium heparin) using the Atellica® CI Analyzer. The Atellica IM CHIV assay is intended to be used as an aid in the diagnosis of HIV infection in pediatric and adult populations, including pregnant women. The Atellica IM CHIV assay is not intended for the screening of donors of blood and blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps). Although the effectiveness of the assay for screening blood or plasma donors has not been established, the assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening tests are unavailable, or if their use is impractical. A reactive result using the Atellica IM CHIV assay does not distinguish HIV-1 p24 antigen, HIV-1 antibody, HIV-2 antibody, and HIV-1 group O antibody.	Same
Indications For Use	Same	Same
Measurement	Qualitative	Same
Operating Principle	2-step antigen/antibody sandwich immunoassay	Same

Item	Candidate Device Atellica® IM HIV Ag/Ab Combo (CHIV) assay (on Atellica CI Analyzer)	Predicate Device ADVIA Centaur® HIV Ag/Ab Combo (CHIV) assay (on ADVIA Centaur XP system; BP140103)
Detection Antibody	Lite Reagent: Recombinant HIV antigens (~0.12 µg/mL) and mouse monoclonal anti-HIV antibody (~0.004 µg/mL) labeled with acridinium ester in buffer; bovine serum albumin; mouse IgG; goat serum; surfactant; preservatives Ancillary Lite Reagent: Recombinant HIV antigens (~0.23 µg/mL) and mouse monoclonal anti-HIV antibody (~1.5 µg/mL) labeled with acridinium ester in buffer; bovine serum albumin; mouse IgG; goat serum; surfactant; preservatives	Same
Capture Antibody	Solid Phase: Streptavidin-coated paramagnetic microparticles preformed with biotinylated HIV antigens (~1.5 µg/mL) and biotinylated mouse monoclonal anti-HIV antibodies (~4.5 µg/mL) in buffer; bovine serum albumin; mouse IgG; surfactant; preservatives	Same
Sample Type	Human serum and plasma (potassium EDTA, lithium heparin, sodium heparin)	Same
Sample Volume	100µL	Same
Reagent on Board Stability	35 Days	42 Days
Calibration	2 Levels	Same
Calibrators	Liquid, ready to use	Same
Calibrator On Board Stability	8 hours	Same
Intended Use Population	Pediatric and adult populations, including pregnant women	Same
Cut off Index Value	1.0	Same
Interpretation	Non-reactive, reactive	Same

Similarities and Differences Table for Comparison of ADVIA Centaur XP and Atellica CI Analyzer platforms.

Feature	ADVIA Centaur XP® (cleared under K041133)	Atellica® CI (cleared under K222116)
SIMILARITIES		
Optical System	PMT used in photon counting mode	Same
Intended Use	Automated, immunoassay analyzer designed to perform in vitro diagnostic tests	Same

Feature	ADVIA Centaur XP® (cleared under K041133)	Atellica® CI (cleared under K222116)
Operating Assay Principle	Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	Same
Type of System	Random access and batch	Same
Test Processing	Sample scheduling optimized for throughput; continuous operation	
	Reactions are controlled at 37°C	
Sample Handling		
Sample Container	Sample cups or primary tubes	Same
Sample Type	Serum, plasma, urine, whole blood hemolysate, amniotic fluid	Same
Sample Pipette	Disposable sample pipette tips	Same
Dispense System	Automated pipetting of samples using precision syringe	Same
Sample Probe	Air pressure fluid sensing and disposable tip sensing; clog detection mechanism to alert operator to clogged sample probe	Same
Dilutions	Allowed on a per-assay basis; capability of dilution of samples requiring pretreatment	Same
Reagent Handling		
Dispense system	Automated pipetting using precision syringes	Same
Mixing	Reagents mixed via rocking platform	Same
Reagents	Primary Reagent Pack has separate wells for Solid Phase, Lite Reagent and Ancillary reagents	Same (identical reagent formulation)
	Ancillary Reagent Pack – contains components of the active reagent and/or sample diluents	Same (identical reagent formulation). Modification in container shape (Uses the Atellica IM ancillary reagent packs)
Calibration		
Reagent	6 to 10-point stored calibration for each reagent	Same
	2-point user run calibration	
Calibrators	Calibrators checked with barcode	Same
	Calibrator lot numbers stored and displayed	
Controls	Capability to run controls and track results	Same

Feature	ADVIA Centaur XP® (cleared under K041133)	Atellica® CI (cleared under K222116)
DIFFERENCES		
Throughput Rate	120 to 240 tests/hr	75 to150 tests/hr
Time to First Result	18 min. to 56 min. depending upon assay protocol	10 min. to 55 min. depending upon the assay protocol
Ambient Temperature and Humidity Range	18 - 30°C, 20 - 80% RH	18 - 30°C, 20 - 80% RH. Fluids and air under the system cover are temperature controlled.
Test Processing	7.5-minute incubation, single step	"Fast 1-pass" assays: 8-minute incubation
	20-minute incubation, single step	“Routine 1-pass” assays: 12-minute incubation
	7.5 minute - 20-minute incubation, two step	Not Applicable
	20-minute - 20-minute incubation, two step	“2-pass” assay: 12 minute - 12-minute incubations or 12 minute - 20-minute incubations
Sample Handling		
Sample Volume	10 to 200 µL	10 to 100 µL
Sample Rack	5 tube racks hold sample tubes	6 tube racks hold sample tubes
	The Sample Input, In-Process and Output Queue holds up to 180 samples	The sample Input, In-Process and Output Queue holds up to 132 samples
	Tube size selected on sample tube rack using an encoded barcode with the additional capability of multiple size tubes on the same rack	Tube size identified by Atellica Direct Load 2.0
Reagent Handling		
Assay Reagent Tray	Refrigerated with 30 positions	Refrigerated with 20 positions
	Reagent Pack contains both Solid Phase and Tracer Reagent in separate wells	Reagent Pack contains both Solid Phase and Tracer Reagent in separate wells
Ancillary Reagent Tray	Mobile refrigerated tray with 25 positions	Stationary refrigerated tray with 20 positions

Feature	ADVIA Centaur XP® (cleared under K041133)	Atellica® CI (cleared under K222116)
Reagent Storage	4°C to 8°C	4°C to 10°C
System Bulk Fluids	Wash 1, Acid, Base and Cleaner	Same (identical reagent formulation). Wash,
		Modifications in container size and shape (same AIM Bulk Fluid containers)
Reagent Probes	Three probes	One probe
	Reagent preheating	No reagent preheating
	No level sense	No Level sense
	Probe sent to bottom of container	Probe sent to bottom of container
	Fluid monitoring during aspiration	Fluid monitoring on aspiration and dispense using liquid pressure sensing

9. Non-Clinical and Clinical Test Summary & Conclusions

The reagent formulations of the Atellica IM HIV Ag/Ab Combo (CHIV) assay used on the Atellica CI Analyzer are the same as those of the ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay used on the ADVIA Centaur XP system. Some performance characteristics were established using the ADVIA Centaur XP system (PMA BP140103 and BP140103/8).

Precision

The Precision study was performed in accordance with the guidelines in CLSI EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition*. Samples were assayed on two Atellica CI Analyzers in duplicate in two runs per day for 20 days at one site with one reagent lot, producing a total of 80 measurements. The study assessed a ten-member sample panel for HIV antibody, a two-member panel for HIV-1 antigen and two negative samples. Repeatability and within-laboratory precision were determined using a nested, two factor (days and runs nested within days) ANOVA model. Each system was analyzed separately. The following results were obtained:

		Repeatability		Within-Laboratory precision	
Sample Type	**Mean of 80 reps (Index)**	**SD (Index)**	**% CV**	**SD (Index)**	**% CV**
Serum A	0.16	0.012	7.5	0.014	8.8
Serum B	2.93	0.068	2.3	0.123	4.2
Serum C	4.92	0.079	1.6	0.180	3.7

Serum D	2.76	0.060	2.2	0.157	5.7
Serum E	1.48	0.023	1.6	0.045	3.0
Serum F	3.38	0.069	2.0	0.107	3.2
Serum G	0.72	0.026	3.6	0.030	4.2
Serum H	1.17	0.038	3.2	0.042	3.6
Serum I	4.92	0.077	1.6	0.152	3.1
Control 1	0.26	0.015	5.8	0.016	6.2
Control 2	4.99	0.097	1.9	0.120	2.4
Control 3	2.94	0.046	1.6	0.083	2.8
Control 4	3.07	0.052	1.7	0.140	4.6
Control 5	2.41	0.038	1.6	0.089	3.7

The repeatability and within-laboratory precision study results using the Atellica CI analyzer (candidate) were within the acceptance criteria for all samples tested and demonstrated equivalent performance to the ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay (predicate) on ADVIA Centaur XP system.

Reproducibility

The reproducibility study design consisted of three sites, five days, two runs per day, and three replicates per run using one reagent lot. A panel of 14 samples, consisting of two negative and 12 positive samples for either HIV antibody or HIV-1 antigen . Results were analyzed by individual site as well as all three sites combined.

The following are the reproducibility results of the Atellica IM CHIV assay on Atellica CI Analyzers at three sites:

System: Atellica CI Analyzer			**Repeatability**		**Between-Run**		**Between-Day**		**Between-Site**		**Reproducibility**	
Sample	**n**	**Mean (Index)**	**SD (Index)**	**%CV**	**SD (Index)**	**%CV**	**SD (Index)**	**%CV**	**SD (Index)**	**%CV**	**SD (Index)**	**%CV**
Negative Control	85*	0.14	0.033	23.6	0.022	15.7	0.010	7.1	0.031	22.1	0.052	37.1
HIV-1 Control	90	5.15	0.158	3.1	0.000	0.0	0.055	1.1	0.069	1.3	0.181	3.5
HIV-2 Control	90	3.19	0.090	2.8	0.064	2.0	0.046	1.4	0.126	3.9	0.174	5.5
Group O Control	90	6.32	0.344	5.4	0.000	0.0	0.000	0.0	0.426	6.7	0.547	8.7
P24 Antigen Control	90	3.52	0.109	3.1	0.045	1.3	0.050	1.4	0.082	2.3	0.153	4.3
Negative Serum Pool 9	89*	0.18	0.030	16.7	0.003	1.7	0.028	15.6	0.014	7.8	0.043	23.9
P24 Antigen Serum Pool 7	90	3.94	0.120	3.0	0.052	1.3	0.072	1.8	0.155	3.9	0.215	5.5
P24 Antigen Serum Pool 8	90	7.13	0.179	2.5	0.096	1.3	0.078	1.1	0.287	4.0	0.360	5.0
Group O Serum Pool 6	90	5.84	0.245	4.2	0.198	3.4	0.000	0.0	0.333	5.7	0.458	7.8
HIV-2 Serum Pool 4	90	1.47	0.053	3.6	0.007	0.5	0.046	3.1	0.064	4.4	0.095	6.5
HIV-2 Serum Pool 5	90	3.79	0.110	2.9	0.044	1.2	0.066	1.7	0.120	3.2	0.181	4.8
HIV-1 Serum Pool 1	90	0.55	0.034	6.2	0.000	0.0	0.023	4.2	0.044	8.0	0.060	10.9
HIV-1 Serum Pool 2	90	1.02	0.047	4.6	0.017	1.7	0.018	1.8	0.024	2.4	0.059	5.8
HIV-1 Serum Pool 3	90	5.89	0.142	2.4	0.000	0.0	0.059	1.0	0.122	2.1	0.196	3.3

* At least 1 result was out of the measuring interval.

The reproducibility results for the Atellica IM CHIV assay on the Atellica CI Analyzer (candidate) were within the acceptance criteria for all samples tested and demonstrated equivalent performance to the ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay on ADVIA Centaur XP system (predicate).

WHO p24 Detection

Analytical sensitivity of the Atellica IM CHIV assay when used on the Atellica CI analyzer for HIV-1 p24 antigen was determined using the WHO International Standard, NIBSC code: 90/636 at the CHIV cutoff of 1.00 Index. The standard was reconstituted in 1.0 mL of distilled water to a concentration of 1000 IU/mL and then diluted 40-fold using a p24 antigen-negative human serum pool and subsequently serially diluted 2-fold using the same negative serum pool.

Each sample was assayed in four replicates on one test day. Concentrations were determined using a single 2-point calibration for each lot and analyzer. The study was performed with two reagent lots, one on Atellica CI Analyzer and one on ADVIA Centaur XP system. The p24 antigen concentration at the CHIV cutoff of 1.00 Index was calculated from the linear regression equation for each analyzer and lot. The results using the Atellica CI Analyzer were compared to those of the ADVIA Centaur XP system. Table below summarizes the p24 antigen concentration at the CHIV cutoff of 1.00 Index calculated from the regression equations for each lot and analyzer.

Platform	Reagent Lot	Slope	Intercept	R^2	p24 Concentration at 1.00 Index (IU/mL)
Atellica CI	1	1.9155	-0.5645	0.998	1.35
ADVIA Centaur XP	1	1.8272	-0.5913	.0998	1.24
Atellica CI	2	1.5320	-0.3437	0.999	1.19
ADVIA Centaur XP	2	1.5053	-0.3573	0.998	1.15

The HIV-1 p24 Antigen sensitivity, 1st International Reference Reagent concentration at the Atellica IM CHIV assay cut-off value is 1.35 IU/mL on the Atellica CI Analyzer and 1.24 IU/mL for the ADVIA Centaur XP system. The performance of the Atellica CI Analyzer (candidate) demonstrated equivalent performance to the ADVIA Centaur XP system (predicate).

Dilutional Sensitivity

Eight serial dilution panels for HIV-1 Group O, 9 panels for HIV-2,and 10 panels each for HIV (unspecified type) and HIV-1 were tested in singlicate on both the Atellica CI Analyzer and ADVIA Centaur XP system platforms over five days. The dilution panels were prepared by serially diluting sample to a final dilution factor of 64 in HIV negative human serum. Concentrations were determined using a single 2-point calibration for each analyzer. The study was performed with one reagent lot of Atellica IM CHIV assay on one Atellica CI Analyzer and one ADVIA Centaur XP system platform. Data were evaluated by comparison of the Atellica CI Analyzer results to those of the ADVIA Centaur XP system. The first dilution

where the sample result was nonreactive marked the dilutional sensitivity point, which was compared with that of the ADVIA Centaur XP system.

For HIV-1 HIV (unspecified type) and HIV Group O samples, the Atellica IM CHIV assay and the ADVIA Centaur CHIV assay dilutional sensitivity ranged from 1/16 to 1/32. For the HIV-2 samples, dilutional sensitivity ranged from 1/2 to 1/64 for both assays. There was no difference in sensitivity between the systems.

The Atellica IM CHIV assay on the Atellica CI Analyzer (candidate) had the same dilutional sensitivity point as the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system (predicate) for all samples tested. The performance of the Atellica CI Analyzer at low analyte levels demonstrated equivalent performance to the ADVIA Centaur XP system.

Carry-Over

Three reagent pairs were used with Atellica IM CHIV assay on the Atellica CI Analyzer to evaluate carry-over. Negative and positive human serum pool controls were assayed in 10 replicates each to establish baseline values for the testing. Ten replicate each controls were run, followed by alternating high and low controls, followed by five replicates of each control. Sample concentrations were determined using a single 2-point calibration. The study was performed using one reagent lot on one Atellica CI Analyzer. The average of the first 10 replicates, the 10 alternated replicates and the five final replicates were calculated for each control.

The verification data collected met the acceptance criteria and demonstrated that the reagent carryover mitigations for the Atellica IM CHIV assay were effective on the Atellica CI analyzer.

Clinical Performance

Clinical Sensitivity and Specificity data is available in PMA approval for ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay on the ADVIA Centaur XP system (PMA Number BP140103).

Detection of HIV-1 and HIV-2 Antigen Subtypes

Data on detection of HIV-1 and HIV-2 antigen subtypes is available in PMA approval for ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay (PMA Number BP140103).

Genotype Study

Data on genotype is available in PMA approval for ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay (PMA Number BP140103).

Interference

The analytical specificity/interference for the Atellica IM CHIV assay on the Atellica CI analyzer was evaluated on the ADVIA Centaur XP system under PMA BP140103. This Atellica IM CHIV assay run on the Atellica CI Analyzer is the identical Atellica IM CHIV assay under PMA Supplement BP140103/8 for Atellica IM CHIV assay on Atellica IM Analyzer.

This data is available in PMA approval for ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay (PMA Number BP140103).

Cross-Reactivity

Data on cross-reactivity is available in PMA approval for ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay (PMA Number BP140103).

Specimen Equivalency

Data on specimen equivalency is available in PMA approval for ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay (PMA Number BP140103).

Seroconversion Panels

Twenty commercially available seroconversion panels were tested using the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system and the Atellica IM CHIV assay on an Atellica CI Analyzer. Seroconversion panel performance was tested according to the guidelines of the CLSI EP09C-ED3: *Measurement Procedure Comparison and Bias Estimation Using Patient Samples* and CLSI EP12-A2: *User Protocol for Evaluation of Qualitative Test Performance*. Samples were assayed in one replicate on the Atellica CI Analyzer and ADVIA Centaur system. Testing was completed over four days using a single 2-point calibration per analyzer/system. Each panel was tested with one of two reagent lots on one of three Atellica CI Analyzers and one ADVIA Centaur XP system. The performance of the Atellica IM CHIV assay on the seroconversion panels matched the performance of the ADVIA Centaur CHIV assay. The following results were obtained:

Panel ID	CHIV Reactive Results From Initial Draw Date		ADVIA Centaur XP system vs Atellica CI Analyzer
	ADVIA Centaur Assay (Days)	Atellica CI Assay (Days)	Difference in Bleed Number (Bleeds)
62216	22	22	0
63215	24	24	0
63753	66	66	0
64578	25	25	0
65376	16	16	0
65389	16	16	0
65522	12	12	0
65685	38	38	0
66048	146	146	0
66575	28	28	0
66632	50	50	0
68106	38	38	0
68205	44	44	0

Panel ID	CHIV Reactive Results From Initial Draw Date		ADVIA Centaur XP system vs Atellica CI Analyzer
	ADVIA Centaur Assay (Days)	Atellica CI Assay (Days)	Difference in Bleed Number (Bleeds)
68582	47	47	0
73695	119	119	0
73698	28	28	0
75062	40	40	0
77600	49	49	0
77840	13	13	0
1043487	7	7	0

The Atellica CI Analyzer seroconversion results are equivalent to the seroconversion results generated using the ADVIA Centaur XP system. Therefore, Atellica CI Analyzer (candidate) has comparable seroconversion sensitivity as the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system (predicate).

High Dose Hook

High anti-HIV antibody concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect) from a sample. Anti-HIV-1 and anti-HIV-2 positive samples with a value > 1000 Index were tested using the Atellica IM CHIV assay on the Atellica CI Analyzer and the samples reported an Index > 12.00. No hook effect was observed for patient samples with a value > 1000 Index.

Recombinant p24 antigen spiked into a negative sample was tested using the Atellica IM CHIV assay on the Atellica CI Analyzer and the sample reported a value > 12.00 Index. At 1 µg/mL of p24 antigen, no hook effect was observed.

Stability

The Atellica IM HIV Ag/Ab Combo (CHIV) reagents and calibrators are stable through the expiration date on the product when stored at 2-8 °C. Calibrators are stable for 8 hours at room temperature per the original PMA (BP140103).

On-Board Stability (OBS) and Pack Calibration Interval (In-Use) stability was evaluated for the Atellica IM CHIV assay when used with the Atellica CI analyzer according to the guidelines of the CLSI EP25-A: *Evaluation of Stability of In Vitro Diagnostic Reagent*s.

The results demonstrate that the Atellica IM CHIV assay is stable onboard the Atellica CI Analyzer for 35 days with a pack calibration interval of 35 days.

Clinical Performance

Clinical Sensitivity:

A total of 993 confirmed HIV positive samples were tested in the Atellica CHIV assay on the Atellica CI Analyzer, out of which 99.80% (991/993) were initially reactive. A total of 926 had sufficient volume for further testing and this resulted in a repeat reactive rate of 99.78% (924/926).

Of the 965 samples tested with the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system, 99.79% (963/965) were initially reactive. Of these samples, 933 had sufficient volume for further testing and this resulted in a repeat reactive rate of 99.79% (931/933).

	Atellica CI Analyzer					ADVIA Centaur XP System					Repeatedly Reactive Specimens (Number Reactive Positive by Method)	
	Initial			Final Algorithm		Initial			Final Algorithm			
Category	N Samples	Non-Reactive	Reactive	N Samples	Repeatedly Reactive	N Samples	Non-Reactive	Reactive	N Samples	Repeatedly Reactive	HIV-1 HIV-2 Ab Diff	HIV-1 Qual RNA
Group O Contrived	6	0	6	6	6	5	0	5	4	4	0	0
Group O Native	50	0	50	48	48	48	0	48	34	34	0	0
HIV Positive Pediatric	50	0	50	50	50	50	0	50	45	45	0	0
HIV Positive Pregnant	37	0	37	37	37	37	0	37	37	37	0	0
HIV-1 Pos	601	0	601	536	536	576	0	576	568	568	0	0
HIV-2 Positive	197	0	197	197	197	197	0	197	193	193	0	0
p24 Contrived	37	0	37	37	37	37	0	37	37	37	0	0
p24 Native	15	2	13	15	13	15	2	13	15	13	0	0
Total	993	2	991	926	924	965	2	963	933	931	0	0
Total (%)		0.20%	99.80%		99.78%		0.21%	99.79%		99.79%		

The overall clinical sensitivity of the Atellica CHIV assay on the Atellica CI Analyzer CHIV assay was 99.78% (924/926, 95% CI of 99.22% - 99.97%) upon repeat testing.

The overall clinical sensitivity of the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system was 99.79% (931/933, 95% CI of 99.23% - 99.97%) upon repeat testing.

The clinical sensitivity of the Atellica IM CHIV assay on the Atellica CI Analyzer met the acceptance criteria. The study results demonstrate that the clinical sensitivity is comparable between the Atellica CI Analyzer and the ADVIA Centaur XP system.

Clinical Specificity:

A total of 2509 samples from apparently healthy, low-risk and high-risk population were tested on the Atellica CHIV assay on the Atellica CI Analyzer for this study. Seven out of 2509

samples were initially reactive, and six were repeat reactive. These six samples were confirmed negative by confirmatory test. Two samples were negative on the Atellica CI Analyzer and positive on the ADVIA Centaur XP system. Following the algorithm, both samples were repeat reactive on the ADVIA Centaur XP system and further confirmatory testing confirmed these samples are HIV-positive. The samples were removed from the specificity calculation.

Of the 2492 samples tested on the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system, 99.56% (2481/2492) of the overall pooled population including apparently healthy, low-risk and high-risk population were non-reactive. Eleven samples out of 2492 were initially reactive, and nine out of 2492 samples were repeatedly reactive. Of nine repeatedly reactive samples, two were found positive by confirmatory testing. The results from these two specimens were excluded from the specificity calculation.

	Atellica CI Analyzer					**ADVIA Centaur XP System**					**Repeatedly Reactive Specimens (Number Reactive Positive by Method)**	
	Initial			**Final Algorithm**		**Initial**			**Final Algorithm**			
Category	**N Samples**	**Non-Reactive**	**Reactive**	**N Samples**	**Repeatedly Reactive**	**N Samples**	**Non-Reactive**	**Reactive**	**N Samples**	**Repeatedly Reactive**	**HIV-1 HIV-2 Ab Diff**	**HIV-1 Qual RNA**
Apparently Healthy	734	734	0	734	0	730	729	1	730	1	1	0
Apparently Healthy Pregnant	249	249	0	249	0	246	246	0	246	0	0	0
Hospital Specimen	50	50	0	50	0	50	49	1	50	1	1	0
Low HIV Risk Pediatric	75	75	0	75	0	74	74	0	74	0	0	0
High-Risk	1401	1394	7	1400	6	1392	1383	9	1392	7	0	0
Total	2509	2502	7	2508	6	2492	2481	11	2492	9	2	0
Total (%)		99.72%	0.28%		0.24%		99.56%	0.44%		0.36%		

The Atellica CHIV assay on the Atellica CI Analyzer clinical specificity for the overall pooled population was 99.76% (2500/2506) with a 95% confidence interval of 99.48% - 99.91% upon repeat testing.

The ADVIA Centaur CHIV assay on the ADVIA Centaur XP clinical specificity for the overall pooled population was 99.72% (2483/2490) with a 95% confidence interval of 99.42% - 99.89% upon repeat testing.

The Atellica CI Analyzer clinical specificity for the overall pooled populations met the acceptance criteria. The study results demonstrate that the clinical specificity is comparable between the Atellica CI Analyzer and the ADVIA Centaur XP system.

Other clinical supportive data:

The percent agreement between the Atellica CHIV assay on the Atellica CI Analyzer and the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system was evaluated by testing a total of 3456 samples in singlicate across three clinical testing sites on an Atellica CI Analyzer and an ADVIA Centaur XP system. One lot of ADVIA Centaur CHIV reagents, calibrators, and controls and one lot of Atellica IM CHIV reagents, calibrators, and controls were used for the testing. The concordance analysis, based on the final test results for the Atellica CI Analyzer and the ADVIA Centaur XP system, is summarized in the tables below.

Atellica CI Analyzer	**ADVIA Centaur XP system**		
	Nonreactive	**Reactive**	**Total**
Nonreactive	2483	3	2486
Reactive	1	887	888
Total	2484	890	3374

	Atellica CI Analyzer/ ADVIA Centaur XP system	**Agreement (%)**	**95% Confidence Interval**
Nonreactive (Negative)	2483/2484	99.96%	99.78%-100.00%
Reactive (Positive)	887/890	99.66%	99.02%-99.93%

The results for the positive and negative percent agreements between the Atellica CHIV assay on the Atellica CI Analyzer (candidate) and the ADVIA Centaur CHIV assay on the ADVIA Centaur XP system (predicate) met the acceptance criteria. The assay performance between the Atellica CI Analyzer and the ADVIA Centaur XP system is therefore comparable.

10. Conclusions

Clinical and non-clinical, instrument-specific analytical studies were performed to demonstrate the performance of the Atellica IM HIV Ag/Ab Combo (CHIV) assay on the Atellica CI Analyzer. The data from analytical and clinical performance testing support a conclusion of substantial equivalence between the Atellica IM HIV Ag/Ab Combo (CHIV) assay on the Atellica CI Analyzer (candidate) and ADVIA Centaur HIV Ag/Ab Combo (CHIV) assay on the ADVIA Centaur XP system (predicate).