510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name: LIAISON® MUREX HIV Ab-Ag HT
LIAISON® MUREX Control HIV Ab-Ag HT

Common Names/Description: HIV Ab-Ag Assay and HIV Ab-Ag Control

Classification: Human immunodeficiency virus (HIV) serological diagnostic and/or supplemental test: 21 CFR 866.3956; Class II (performance standards); Microbiology (83)
Quality Control Material: 21 CFR 862.1660; Class I;

Product Code: MZF

PREDICATE DEVICE: LIAISON® XL MUREX HIV Ab/Ag HT; LIAISON® XL MUREX Control HIV Ab/Ag HT (BP190437)

DEVICE DESCRIPTION:
The LIAISON® MUREX HIV Ab/Ag HT is an in vitro chemiluminescent immunoassay for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human serum or plasma.
For In Vitro Diagnostic Use.
For Prescription Use Only.

The LIAISON® MUREX Control HIV Ab/Ag HT set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® MUREX HIV Ab/Ag HT assay.

The assay and controls are designed for use with the DiaSorin LIAISON® XL and LIAISON® XS.

INTENDED USE(s):
The LIAISON® MUREX HIV Ab/Ag HT is an in vitro chemiluminescent immunoassay for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human serum (without or with gel-SST) or plasma (lithium and sodium heparin, sodium citrate, and potassium EDTA), on the LIAISON® XL Analyzer or LIAISON® XS Analyzer. It is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pediatric subjects (2-21 years) and in pregnant women.

The assay cannot distinguish between the detection of HIV p24 antigen and HIV-1/HIV-2 antibodies.

The LIAISON® MUREX HIV Ab/Ag HT assay is not intended for screening donors of blood or blood products, or human cells or tissues or cellular and tissue-based products (HCT/Ps), or organ donors for HIV.

The LIAISON® MUREX Control HIV Ab/Ag HT is intended for use as assayed quality control samples to monitor the performance of the LIAISON® MUREX HIV Ab/Ag HT assay. The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON® XL and LIAISON® XS.

COMPARISON TO THE PREDICATE (Description of the Modifications to the Legally Marketed Device):

Modifications to the DiaSorin LIAISON® XL MUREX HIV Ab/Ag HT assay include:

- Addition of LIAISON® XS Analyzer

The following tables provide a summary of the similarities and differences between the FDA cleared LIAISON® XL MUREX HIV Ab/Ag HT, LIAISON® XL MUREX Control HIV Ab/Ag HT and the modified devices.

Table of Similarities LIAISON® MUREX HIV Ab/Ag HT		
Characteristic	**Predicate Device DiaSorin LIAISON® XL MUREX HIV Ab/Ag HT BP190437, approved 11/25/2020**	**Modified Device DiaSorin LIAISON® MUREX HIV Ab/Ag HT**
Technology/ Assay Principle	Chemiluminescent Immunoassay (CLIA)	Same
Sample Handling/Assay Processing	Automated	Same
Manufacturing Process	No Change	Same
Storage	Store at 2-8º C until ready to use	Same
Measured Analyte	HIV p24 antigen and antibodies to HIV-1 and HIV-2	Same
Sample Volume	350 µL specimen (200 µL specimen + 150 µL dead volume)	Same
Assay Procedure	• Dispense calibrators, controls or specimens into the reaction cuvettes. • Dispense coated magnetic particles. • Dispense Assay Buffer. • Incubate. • Wash with Wash/System liquid. • Dispense Conjugate into the reaction cuvettes. • Incubate. • Wash with Wash/System liquid. • Add the Starter Reagents and measure the light emitted.	Same

Measurement System	Photomultiplier (flash chemiluminescence reader)	Same
Calibrators	Included with kit	Same
Open Use/On Board Stability	Five (5) weeks when stored at 2–8°C or on board the analyzer.	Same
Calibration Stability	Five (5) weeks	Same
Controls	Provided Separately	Same
Sample Storage at 2-8°C	If the assay is performed within seven (7) days of sample collection, the samples may be kept at 2–8°C	Same
Serum Storage Freeze-Thaw Cycles	Samples are stable through seven (7) freeze/thaw cycles	Same
Reagent Integral Configuration and Volume Provided	• Magnetic particles – 1 compartment (2.5 mL) • Calibrator – 1 compartment (2.9 mL) • Assay buffer – 1 compartment (10.8 mL) • Conjugate – 2 compartments (23 mL each compartment)	Same
Raw materials		
Sample Type	Human Serum or Plasma	Same
Tests per Kit	200	Same
Cut-Off	1.00 S/CO	Same
Calibration	Calibration by using fully qualitative approach	Same
Unit of Measure	Signal/Cut-off (S/CO)	Same

Table of Differences LIAISON® MUREX HIV Ab/Ag HT		
Characteristic	**Predicate Device DiaSorin LIAISON® XL MUREX HIV Ab/Ag HT BP190437, approved 11/25/2020**	**Modified Device DiaSorin LIAISON® MUREX HIV Ab/Ag HT**
Intended Use/Indications for Use	The LIAISON® XL MUREX HIV Ab/Ag HT is an in vitro chemiluminescent immunoassay for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human adult and pediatric (2 – 21 years) serum or plasma (lithium and sodium heparin, sodium citrate and potassium EDTA) including separator tubes, on the LIAISON® XL Analyzer.	The LIAISON® MUREX HIV Ab/Ag HT is an *in vitro* chemiluminescent immunoassay for the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human serum (without or with gel-SST) or plasma (lithium and sodium heparin, sodium citrate, and potassium EDTA), on the LIAISON® XL Analyzer or LIAISON® XS Analyzer.

	It is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pediatric subjects and in pregnant women. The assay cannot distinguish between the detection of HIV antigen and HIV-1/HIV-2 antibodies. The LIAISON® XL MUREX HIV Ab/Ag HT assay is not intended for the screening blood, blood products, or human cells or tissues or cellular and tissue-based products (HCT/Ps), or organ donors for HIV.	It is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pediatric subjects (2-21 years) and in pregnant women. The assay cannot distinguish between the detection of HIV p24 antigen and HIV-1/HIV-2 antibodies. The LIAISON® MUREX HIV Ab/Ag HT assay is not intended for screening donors of blood or blood products, or human cells or tissues or cellular and tissue-based products (HCT/Ps), or organ donors for HIV.
Instrument Platform	LIAISON® XL (Free standing)	LIAISON® XL (Free standing) and LIAISON® XS (Benchtop)

Table of Similarities and Differences LIAISON® MUREX Control HIV Ab/Ag HT		
Characteristic	**Predicate Device DiaSorin LIAISON® XL MUREX Control HIV Ab/Ag HT BP190437, approved 11/25/2020**	**Modified Device DiaSorin LIAISON® MUREX Control HIV Ab/Ag HT**
Intended Use	The LIAISON® XL MUREX Control HIV Ab/Ag HT is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL HIV Ab/Ag HT assay. The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON® XL.	The LIAISON® MUREX Control HIV Ab/Ag HT is intended for use as assayed quality control samples to monitor the performance of the LIAISON® MUREX HIV Ab/Ag HT assay. The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON® XL and LIAISON® XS.
Negative Control	Human serum non-reactive for HIV antigens and antibodies, 0.2% ProClin™ 300, preservatives.	Same
POSITIVE CONTROL (anti-HIV-2)	Human serum/plasma reactive for HIV-2 antibodies, 0.2% ProClin™ 300, preservatives.	Same
POSITIVE CONTROL (anti-HIV-1O)	Rabbit polyclonal reactive for HIV-1O antibodies, human serum, 0.2% ProClin™ 300, preservatives.	Same
POSITIVE CONTROL (anti-HIV-1M)	Human serum/plasma reactive for HIV-1M antibodies, 0.2% ProClin™ 300, preservatives.	Same

POSITIVE CONTROL (HIV/Ag)	HIV p24 recombinant antigen (obtained in E.coli), stabilized in PBS buffer, bovine aprotinin, casein, 0.2% ProClin™ 300.	Same
Reagent Configuration	1 vial of each level, 4.5 mL/vial, ready to use.	Same
Storage	Store at 2-8º C until ready to use	Same
Open Use Stability	After removing the seals, the control vial is stable for nine (9) weeks when stored upright at 2–8°C.	Same

SUMMARY OF PERFORMANCE DATA:

A summary of nonclinical performance testing associated with the DiaSorin LIAISON® MUREX HIV Ab/Ag HT assay on the LIAISON XS Analyzer is as follows:

1. Analytical Sensitivity: Seroconversion Panel

The purpose of the analytical sensitivity testing was to define the limits of an assay at low concentrations.

Analytical sensitivity testing was carried out with one (1) kit lot on one (1) LIAISON® XS unit and one (1) LIAISON® XL unit. It was evaluated by testing twenty (20) seroconversion panels across the two platforms which had previously been tested for the LIAISON® XL original PMA BP190437. Note: one (1) panel had not been previously tested but was run as no other panel from the PMA was available for procurement. The seroconversion samples were tested in singlicate, and controls (LIAISON® MUREX Control HIV Ab/Ag HT) used to validate the days' runs. The results were compared with information reported in Certificate of Analysis.

All twenty (20) seroconversion panels gave comparable results on the LIAISON® XS compared to the LIAISON® XL and matched the competitor assay from the CoA. The seroconversion sensitivity study demonstrated no discrepant results for the DiaSorin LIAISON® MUREX HIV Ab/Ag HT assay on the LIAISON® XS Analyzer versus the LIAISON® XL Analyzer.

2. Analytical Sensitivity: Detectable Concentration at Cut-off Level

The analytical sensitivity representing the cut-off dose in term of IU/ml, was evaluated by testing the WHO International Standard HIV-1 p24 Antigen, 1st International Reference Reagent (NIBSC code: 22/230).

The testing was carried out with one (1) kit lot on two (2) LIAISON® XS units. The analytical sensitivity of the assay was evaluated using serial dilutions of the WHO International Standard HIV-1 p24 Antigen, 1st International Reference Reagent (NIBSC code: 22/230) in both serum and plasma.

Results obtained were analyzed by linear regression analysis: the cut-off dose was identified as the dose corresponding to S/CO = 1.00 on the regression line; the final sensitivity value corresponded to the overall mean value.

The analytical sensitivity in terms of IU/mL, when the S/CO = 1.00, has been calculated for serum on one (1) LIAISON® XS as 1.170 IU/mL and on the other LIAISON® XS as 1.132 IU/mL. For plasma, the analytical sensitivity has been calculated on one (1) LIAISON® XS as 1.154 IU/mL and on the other LIAISON® XS as 1.086 IU/mL. These results demonstrated comparable analytical sensitivity performance to the LIAISON® XL.

3. Method Comparison

A total of 355 specimens were analyzed for method comparison. Of these 355 specimens, 271 were native serum or plasma specimens and 84 samples were contrived to obtain antibody and/or antigen levels near the cut-off. To contrive the samples, either a unique negative specimen or a pool of unique negative specimens was blended with one (1) unique positive specimen per negative sample. Contrived samples (including the spiker or base units) were not included as neat samples in the method comparison.

Method comparison specimens were randomly divided across three (3) testing sites with equal numbers of samples per site for testing by the candidate device (LIAISON® MUREX HIV Ab/Ag HT assay on LIAISON® XS). Specimens were tested per the Instructions for Use (IFU) in a single replicate at each of the three (3) sites over a minimum of three (3) days by at least two (2) operators at each site. The specimens were also tested in a single replicate by the LIAISON® MUREX HIV Ab/Ag HT assay on the LIAISON® XL Analyzer, according to the IFU, internally (DSU laboratory) for comparison.

Overall Method Agreement

	All Sites combined	LIAISON® XL			
		NR (n)	IR (n)	RR (n)	Total
LIAISON® XS	NR	125	*8*	5	130
	IR	*4*	*222*	*3**	*224*
	RR	3	*5*	220	225
	Total	128	*230*	225	355

*Two specimens were excluded from the final calculation as they were IR but QNS for repeat testing confirmation.

PPA = (220/225) **97.8%** (*95% CI 94.9% - 99.0%*)
NPA = (125/128) **97.7%** (*95% CI 93.3% - 99.2%*)

DSU Site Method Agreement

LIAISON® MUREX HIV Ab/Ag HT Site: DSU		LIAISON® XL		
		RR	NEG	Total
LIAISON® XS	RR	77	2	79
	NEG	0	43	43
	Total	77	45	122

PPA 100% (77/77) 95% CI (95.2%-100.0%)
NPA 95.6% (43/45) 95% CI (85.2%-98.8%)

KMI Site Method Agreement

LIAISON® MUREX HIV Ab/Ag HT Site: KMI		LIAISON® XL		
		RR	NEG	Total
LIAISON® XS	RR	66	1	67
	NEG	1	47	48
	Total	67	48	115

PPA 98.5% (66/67) 95% CI (92.0%-99.7%)
NPA 97.9% (47/48) 95% CI (89.1%-99.6%)

Pan Site Method Comparison

LIAISON® MUREX HIV Ab/Ag HT Site: Pan		LIAISON® XL		
		RR	NEG	Total
LIAISON® XS	RR	77	0	77
	NEG	4	35	39
	Total	81	35	116

PPA 95.1% (77/81) 95% CI (88.0%-98.1%)
NPA 100% (35/35) 95% CI (90.1%-100.0%)

Summary of Discordant Samples

Sample ID	LIAISON® XL		LIAISON® XS		
	Dose (S/CO)	Final Call	Dose (S/CO)	Final Call	Site
6.7459BCO	0.967	NR	1.19, 1.19, 1.16	RR	DSU
6.7471BCO	0.921	NR	1.09, 1.07, 1.01	RR	KMI
6.8076ACO	0.794	NR	1.06, 1.08, 1.05	RR	DSU
6.7474BCO	1.28, 1.29, 1.14	RR	0.917	NR	Pan
6.7478BCO	1.23, 1.21, 1.19	RR	0.940	NR	Pan
6.7485BCO	1.17, 1.23, 1.17	RR	0.938	NR	Pan
6.8075ACO	1.02, 1.00, 0.916	RR	0.715	NR	Pan
6.8271BCO	1.10, 1.03, 1.07	RR	0.981	NR	KMI

4. 20 Day Precision

Precision testing was carried out on two (2) LIAISON® XS units, using two (2) LIAISON® MUREX HIV Ab/Ag HT (318290) kit lots, a different kit lot was used on each analyzer.

The precision of LIAISON® XL Murex HIV Ab/Ag HT US (318290) on the LIAISON® XS was evaluated using two (2) integral lots and two (2) LIAISON® XS instruments . LIAISON® XL Murex Control HIV Ab/Ag HT US (318291) and a panel of in-house made samples were tested in duplicate, two (2) runs a day, for twenty (20) days. Three samples for each of the four HIV subtypes were evaluated. The within lab precision obtained on the LIAISON® XS was comparable to that on the LIAISON® XL.

Within lab precision study results:

Sample	Mean Dose (S/CO)	N	Repeatability		Between-Run		Between Day		Between-Lot		Within-Lab	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
#71330036	2.56	160	0.042	1.65%	0.040	1.56%	0.034	1.32%	0.30	11.8%	0.224	8.75%
#71340036	2.28	160	0.043	1.88%	0.033	1.46%	0.044	1.91%	0.50	21.7%	0.359	15.7%
#71350036	2.78	160	0.058	2.10%	0.051	1.83%	0.026	0.94%	0.15	5.38%	0.134	4.81%
#71360036	3.15	160	0.050	1.58%	0.027	0.85%	0.036	1.14%	0.20	6.21%	0.154	4.88%
#71370036	0.20	160	0.009	4.39%	0.005	2.41%	0.009	4.46%	0.03	12.7%	0.023	11.2%
HIV3U01 HIV-1 M Ab, high neg	0.87	160	0.021	2.41%	0.012	1.38%	0.013	1.49%	0.19	21.8%	0.137	15.8%
HIV3U02 HIV-1 M Ab, low pos	1.57	160	0.032	2.02%	0.023	1.48%	0.029	1.86%	0.36	23.2%	0.263	16.7%
HIV3U03 HIV-2 Ab, high neg	0.84	160	0.020	2.43%	0.006	0.70%	0.016	1.88%	0.02	2.78%	0.031	3.70%
HIV3U04 HIV-2 Ab, low pos	1.33	160	0.026	1.96%	0.013	0.96%	0.019	1.44%	0.07	5.09%	0.059	4.44%
HIV3U05 HIV-1 O Ab, high neg	0.72	160	0.016	2.15%	0.012	1.61%	0.005	0.69%	0.04	5.28%	0.034	4.65%
HIV3U06 HIV-1	1.31	160	0.026	2.00%	0.021	1.58%	0.012	0.95%	0.05	3.74%	0.050	3.79%

O Ab, low pos												
HIV3U07 HIV p24 Ag, high neg	0.80	160	0.019	2.39%	0.005	0.59%	0.015	1.89%	0.09	11.1%	0.068	8.43%
HIV3U08 HIV p24 Ag, low pos	1.30	160	0.025	1.93%	0.021	1.62%	0.015	1.17%	0.14	10.6%	0.104	8.00%
HIV3U09 HIV-1 M Ab, pos	3.31	160	0.079	2.39%	0.042	1.28%	0.081	2.46%	0.80	24.2%	0.581	17.6%
HIV3U10 HIV-2 Ab, pos	2.32	160	0.038	1.63%	0.022	0.97%	0.049	2.11%	0.16	6.94%	0.131	5.66%
HIV3U11 HIV-1 O Ab, pos	2.48	160	0.043	1.72%	0.032	1.29%	0.024	0.95%	0.12	4.94%	0.105	4.21%
HIV3U12 HIV p24 Ag, pos	2.49	160	0.050	1.99%	0.022	0.90%	0.022	0.86%	0.28	11.3%	0.207	8.32%

5. Reproducibility (5 day precision)

A five (5) day reproducibility study was performed at three (3) clinical sites, one (1) internal and two (2) external. Coded precision panel members, which included one (1) lot of LIAISON® MUREX Control HIV Ab/Ag HT as additional panel members, were tested in one (1) run per day on one (1) LIAISON® XS with six (6) replicates per run at each clinical testing site. Each serum sample panel member (excluding controls) was thawed and tested at each site which had at least two (2) unique operators performing the testing within the five (5) day study. The liquid controls were allowed to reach room temperature prior to use and stored at 2-8°C after each use, per the IFU. The assay was validated each day prior to testing by one replicate of each control generating results within the Certificate of Analysis (COA) range.

The study demonstrated comparable reproducibility on the LIAISON® XS compared to the LIAISON® XL.

Reproducibility

Sample ID	**mean**	**Repeatability (Within Precision)**		**Between Days/Run**		**Within-Site (Laboratory) Precision**		**Between Sites**		**Reproducibility**	
	(S/CO)	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Positive Control HIV Ag (#71330036)	2.39	0.036	1.5%	0.027	1.1%	0.045	1.9%	0.076	3.2%	0.088	3.7%
Positive Control anti-HIV-1M (#71340036)	1.91	0.039	2.0%	0.029	1.5%	0.048	2.5%	0.064	3.4%	0.080	4.2%
Positive Control anti-HIV-1O (#71350036)	2.70	0.054	2.0%	0.032	1.2%	0.063	2.3%	0.082	3.1%	0.104	3.8%
Positive Control anti-HIV-2 (#71360036)	3.28	0.061	1.9%	0.021	0.6%	0.065	2.0%	0.069	2.1%	0.095	2.9%
Negative Control (#71370036)	0.200	0.011	5.5%	0.005	2.6%	0.012	6.1%	0.009	4.6%	0.015	7.6%
HIV3U01 (anti-HIV-1M), high neg	0.759	0.019	2.4%	0.016	2.1%	0.024	3.2%	0.021	2.8%	0.032	4.3%
HIV3U02 (anti-HIV-1M), low pos	1.36	0.029	2.2%	0.025	1.8%	0.038	2.8%	0.046	3.4%	0.060	4.4%
HIV3U03 (anti-HIV-2), high neg	0.848	0.020	2.4%	0.020	2.3%	0.028	3.3%	0.028	3.2%	0.039	4.7%

HIV3U04 (anti-HIV-2), low pos	1.34	0.037	2.7%	0.026	1.9%	0.045	3.3%	0.054	4.1%	0.070	5.3%
HIV3U05 (anti-HIV-1O), high neg	0.718	0.015	2.1%	0.012	1.6%	0.019	2.6%	0.018	2.5%	0.026	3.6%
HIV3U06 (anti-HIV-1O), low pos	1.30	0.035	2.7%	0.023	1.8%	0.042	3.2%	0.041	3.1%	0.058	4.5%
HIV3U07 (p24 Antigen), high neg	0.758	0.016	2.1%	0.021	2.7%	0.026	3.4%	0.016	2.0%	0.030	4.0%
HIV3U08 (p24 Antigen), low pos	1.223	0.023	1.8%	0.009	0.8%	0.024	2.0%	0.032	2.6%	0.041	3.3%
HIV3U09 (anti-HIV-1M), pos	2.78	0.058	2.1%	0.110	4.0%	0.125	4.5%	0.071	2.6%	0.144	5.2%
HIV3U10 (anti-HIV-2), pos	2.345	0.053	2.3%	0.034	1.4%	0.063	2.7%	0.128	5.5%	0.143	6.1%
HIV3U11 (anti-HIV-1O), pos	2.43	0.059	2.4%	0.062	2.6%	0.086	3.5%	0.059	2.4%	0.104	4.3%
HIV3U12 (p24 Antigen), pos	2.37	0.046	2.0%	0.044	1.9%	0.064	2.7%	0.054	2.3%	0.083	3.5%

6. Calibration Stability

A calibration stability study was performed to confirm the performance claim for the new platform.

Calibration stability study was run on one (1) LIAISON® XS Analyzer with one (1) LIAISON® MUREX HIV Ab/Ag HT (318290) integral lot. The integrals were placed on-board the instrument and kept in the reagent area for 36 days, one day more than the calibration stability declared in the IFU (five weeks).

All control results were within their defined ranges up to 36 days: 35 days (as stated in the IFU) plus one day. The linear regression for average percentage difference from T_0 for all samples was within the ±10% limit for the duration of the study - 36 days. Thus, these results confirmed the current IFU claim of calibration stability of 35 days, as stated in the IFU

7. Carryover

The carryover study was carried out to determine whether analyte carryover is present in the LIAISON® MUREX HIV AB/Ag HT US (318290) assay when run on the LIAISON® XS analyzer.

The test was split into two stages, Stage A and Stage B. Both stages were performed on:
• one (1) lot of LIAISON® XL MUREX HIV AB/Ag HT US (318290);
• one (1) lot of LIAISON® XL MUREX Control HIV AB/Ag HT US (318291);
• and on one (1) LIAISON® XS Analyzer.

There is no carryover/cross-contamination observable. The percentage of negative results for the negative sample was 100% for both Stages A and B. The percentage difference between the mean signal (RLU) values of all aliquots in Stage B and Stage A was -0.69%.

8. Additional centrifugation step for sample re-testing

A centrifugation step for all samples that are initially reactive was added to the sample processing steps to reduce the incidence of incorrectly repeatedly reactive samples for the LIAISON MUREX HIV Ab/Ag HT assay. With this extra step, samples requiring repeat testing will be centrifuged at 10,000xg for 10 minutes in a separate tube.

This validation study was performed on the LIAISON® XS and on the LIAISON® XL analyzers using a total of 95 positive samples of the four HIV subtypes (anti-HIV-1 group O, anti-HIV-1 group M, anti-HIV-2, and p24 antigen) in serum and plasma that were run on the LIAISON® XL, including eight samples at the cut-off. All initially reactive samples were split into two aliquots; one aliquot was centrifuged for 10 minutes at 10,000x g and the other aliquot was not centrifuged. The two aliquots of each sample were then tested in duplicate. The average S/CO value of each centrifuged sample was analyzed against the average S/CO value of each non-centrifuged sample, and the initial screening results.

The acceptance criteria were that all samples should maintain their initial classification and the S/CO value of the centrifuged samples should not be significantly different from the S/CO value of both the initial result and of the non-centrifuged duplicate aliquot.

The results were acceptable. All samples that were initially reactive maintained their classification after centrifugation. There was no statistically significant difference between initial, non-centrifuged, and centrifuged samples in plasma. There appeared to be a statistically significant difference between initial and non-centrifuged/centrifuged in serum; however no significant difference was observed between non-centrifuged and centrifuged samples.

9. Interfering Substances

Details of this study can be found in the original PMA BP190437.

10. Sample Matrix

Details of this study can be found in the original PMA BP190437.

11. Sample Handling

Details of this study can be found in the original PMA BP190437.

12. Clinical Performance Evaluation

Details of this study can be found in the original PMA BP190437.

TESTING SUMMARY

Testing and method comparison are complete, the predefined acceptance criteria were met, and data supported the equivalence of the LIAISON® MUREX HIV Ab/Ag HT US on both the LIAISON® XS and the LIAISON® XL platforms.

As the LIAISON® MUREX HIV Ab/Ag HT assay reagents and intended use population have not changed, additional clinical studies were not performed. Non-clinical studies were used to evaluate the performance of the new LIAISON® XS analyzer.

The nonclinical performance testing and method comparison study support a conclusion of substantial equivalence between the LIAISON® MUREX HIV Ab/Ag HT on the candidate (LIAISON® XS) and predicate (LIAISON® XL) analyzers.