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510(k) Summary

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Date prepared: June 3, 2026

Name of device:

Trade Name: LIAISON® Murex HIV Ab/Ag HT
LIAISON® XL
LIAISON® diluteX

Common Name: Test, HIV Detection
Micro chemistry analyzer for clinical use

Classification Name: Human immunodeficiency virus (HIV) serological diagnostic and/or supplemental test: 21 CFR 866.3956, Class II, Microbiology
Analyzer, Chemistry, Micro, For Clinical Use: 21 CFR 862.2170, Class I, Clinical Chemistry

Product Code: MZF
JJF

Predicate Device: LIAISON® Murex HIV Ab/Ag HT (BK241116)
LIAISON® XL (K141116)

Device Description

LIAISON® Murex HIV Ab/Ag HT

The assay simultaneously detects but does not differentiate HIV antibodies and HIV p24 antigen. Qualitative determination of specific antibodies to HIV and HIV p24 antigen is a sandwich chemiluminescence immunoassay. HIV-1 recombinant antigen, HIV-1 group O and HIV-2 biotinylated peptides, and biotinylated monoclonal antibodies to HIV p24 antigen are used for coating magnetic particles (solid phase) and are also linked to isoluminol or fluorescein derivatives (isoluminol antigen/peptides/monoclonal conjugates and fluorescein anti-HIV p24 monoclonal conjugates).

The LIAISON® Murex HIV Ab/Ag HT assay consists of two incubation phases. During the first incubation, HIV antibodies present in samples or controls and HIV p24 antigen present in

calibrator, samples or controls bind to the solid phase and, for HIV p24 antigen, to anti-HIV p24 monoclonal labelled with fluorescein derivatives. During the second incubation, HIV-1 antigen, HIV-1 group O, HIV-2 peptides, monoclonal anti-HIV p24 antigen and monoclonal anti-fluorescein linked to an isoluminol derivative (isoluminol-antigen conjugate) react with HIV antibodies, HIV p24 antigen and monoclonal anti-HIV p24 antigen labelled with fluorescein derivatives already bound to the solid phase. After each incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol antigen/peptide/monoclonal conjugate, is measured by a photomultiplier as relative light units (RLU) and is indicative of HIV-1/2/O antibodies or HIV p24 antigen presence in calibrator, samples or controls.

LIAISON® XL Analyzer with the LIAISON® diluteX
The LIAISON® diluteX is an accessory for the LIAISON® XL analyzer.
The LIAISON® diluteX interfaces with the LIAISON® XL analyzer in order to automatically fill the LIAISON® XL tanks with purified water and properly pre-diluted LIAISON Wash/System Liquid (code 319100). The LIAISON® diluteX enables automatic dilution of the LIAISON® Wash/System Liquid in a range between 1 to 9.5/10.5 from the more concentrated bottled LIAISON® Wash/System liquid. An accurate fluidic system controlled by pressure regulators, pumps, valves and tubes allows the diluted solution to go out of the system and reach the LIAISON® XL analyzer. By the usage of customized caps installed on the LIAISON® XL analyzer, the LIAISON® diluteX is able to automatically refill the diluted solution in the Wash Buffer tank of the LIAISON® XL analyzer. In the same way, the LIAISON® diluteX is able to refill the deionized water tank of LIAISON® XL analyzer.

Intended Use/Indications for Use

The Intended Use/Indications for Use of the device as described in its current labeling (BK241116) has not changed as a result of the modifications.

LIAISON® Murex HIV Ab/Ag HT
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.

LIAISON® XL
The LIAISON® XL Analyzer is a Diagnostic System that measures chemiluminescence. It is intended strictly for professional *in-vitro* Diagnostic use. It is to be used only with Chemiluminescence Immunoassays authorized by DiaSorin Italia S.p.A. for the LIAISON® XL instrument.
The analyzer can be connected to a third-party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays.

LIAISON® diluteX
The LIAISON® diluteX is an accessory for the LIAISON® XL analyzer.
It is designed to automatically dilute the LIAISON® Wash/System Liquid with purified water and to distribute both the purified water and the diluted Wash/System Liquid (referred to as "Wash Buffer") to each connected LIAISON® XL. The LIAISON® diluteX utilizes purified water (referred to as "sourced water"), which must be supplied to the device. The device automatically dilutes the LIAISON® Wash/System Liquid, stored on the device, with the sourced water and distributes both the diluted Wash/System Liquid and the sourced water to the LIAISON® XL via separate tubes directly into the analyzer's tanks.
For professional use only.

Comparison to Predicate Device
The proposed change in this Traditional 510(k) is the introduction of an alternative method for supplying purified water and Wash Buffer to the LIAISON ® XL (LXL) for use the LIAISON® assays, including LIAISON® Murex HIV Ab/Ag HT assay.

Table 1 describes in detail the similarities and differences between the current and manual process of supplying Common Liquids to the LXL and the new automatic method supported by the LIAISON® diluteX. The LXL in the standard configuration is considered as predicate device, while the LXL connected to the LIAISON® diluteX qualifies as the candidate device.

Table 1: Comparison of current process and new process - differences and similarities with the predicate device

Task, step or action	LIAISON® Murex HIV Ab/Ag HT with manual process LIAISON® XL (Predicate device - BK241116)	LIAISON® Murex HIV Ab/Ag HT with the automated process by means of diluteX LIAISON® XL connected to diluteX
Purified Water supply Provision of purified water to the LXL, upon the liquid level reaching a lower threshold in the tank on board the LXL	The LIAISON® XL analyzer (LXL) signals by means of a display on the Graphical User Interface (GUI) the shortage of purified water; The user accesses the lower cabinet and disconnects the purified water tank from the intermediate tank; The user moves the tank to a purified water faucet; The user fills the tank at the purified water faucet; The user returns the tank to cabinet and reconnect it to the LXL; The LXL detects the increased liquid level; The whole process is possible without interruption of the LXL operation, provided the refilling is faster than the exhaustion of the intermediate tank internal to the LXL. Otherwise, The LXL may need more purified water than the residual in the intermediate tank. The LXL SW shall then independently halt the progression of the routine, before any failure in the purified water provision happens.	The diluteX is connected to a purified water source by a dedicate tube; The diluteX, by means of a sensor of its own in the purified water tank of the LXL and completely independent from the LXL, detects the liquid level below a lower threshold; The diluteX then automatically opens a set of valves, allowing the purified water flowing directly from the faucet to the canister by the tube line connected to the LXL tank; The independent sensor in the canister monitors the liquid level until it reaches an upper threshold; At this point, the diluteX switches the valve set and stops the purified water flow; The whole process is possible without interruption of the LXL operation. Errors in feeding are monitored by the independent SW of the diluteX. Once the minimum threshold of water is detected, the LXL Software (SW) shall independently halt the progression of the routine work. The diluteX has no electrical or electronic connection to the XL analyzer and SW of both systems works independent of each other.
Wash Buffer Detection of the liquid level reaching a lower threshold in the tank on board the LXL	The LXL signals by means of a display on the GUI the shortage of Wash Buffer.	The diluteX, by means of a sensor of its own in the tank completely independent from the LXL, detects the liquid level below a lower threshold.

Task, step or action	LIAISON® Murex HIV Ab/Ag HT with manual process LIAISON® XL (Predicate device - BK241116)	LIAISON® Murex HIV Ab/Ag HT with the automated process by means of diluteX LIAISON® XL connected to diluteX
Wash Buffer Preparation of the Wash Buffer from the concentrate	The user accesses the lower cabinet and disconnects the Wash Buffer tank from the intermediate tank; The user manually empties the tank of the remnant of Wash Buffer; The user moves the tank to a purified water faucet; The user rinses the tank and fills the tank at the purified water faucet up to the mark (9 L); The user pours the whole content of a 1 L bottle of LIAISON® Wash/System Liquid in the Wash Buffer tank; The user needs to allow a waiting time of 6 hours to homogenize and degas.	The diluteX is connected to a purified water source by a dedicated tube; The user pours in the LIAISON® Wash/System Liquid tank on the diluteX up to 5 bottles, 1 L each, of concentrate solution; The diluteX, by means of a sensor of its own in the tank completely independent from the LXL, detects the liquid level below a lower threshold; The diluteX automatically opens a set of valves directing the purified water to the dilution pump; The diluteX automatically opens a set of valves directing the LIAISON® Wash/System Liquid to the dilution pump; The dilution pumps add both liquids in a predefined fixed mixing ratio (1 part of the LIAISON® Wash/System Liquid and 9 of purified water) to a mixing line and Wash Buffer intermediate tank. Mixing line and intermediate tank are laid out in a way such that full homogenization is immediately achieved, preventing foam development at the same time. Therefore, the 6-hour waiting time is not required.
Wash Buffer Provision of the Wash Buffer to the LXL	After the 6 hours of waiting time elapsed, the user reconnects the wash buffer-filled tank to the LXL. The LXL detects the increased liquid level. The whole process is possible without interruption of the LXL operation, provided a second prefilled tank is already available when the former is disconnected. Otherwise, during the 6-hour waiting time, the LXL may need more Wash Buffer than the residual in the intermediate tank internal to the LXL. The LXL SW shall then independently halt the progression of the routine, before any failure in the Wash Buffer provision happens.	The diluteX then automatically opens a set of valves, allowing the Wash Buffer to flow directly from the intermediate tank to the canister by the tube line connected to the LXL tank; The independent sensor in the canister monitors the liquid level until it reaches an upper threshold; At this point, the diluteX switches the valve set, stops the dilution pump and stops the Wash Buffer flow; The whole process is possible without interruption of the LXL operation. Errors in the feeding are monitored by the independent SW of the diluteX. Once the minimum threshold level is detected, the LXL SW independently halts the progression of the washing process.

Task, step or action	LIAISON® Murex HIV Ab/Ag HT with manual process LIAISON® XL (Predicate device - BK241116)	LIAISON® Murex HIV Ab/Ag HT with the automated process by means of diluteX LIAISON® XL connected to diluteX
Use of the LIAISON® Wash/System Liquid	The LIAISON® Wash/System Liquid is delivered to the user in 1 L plastic bottles. When needed, a single bottle is poured in a Wash Buffer tank already filled with 9 L of purified water.	The LIAISON® Wash/System Liquid is delivered to the user in 1 L plastic bottles. The content of up to five plastic bottles, for an overall volume of 5 L, can be poured in the dedicated storage tank on the diluteX. The Wash/System liquid in the storage tank is stable for 28 days, and a SW driven maintenance task prompts the user to change the Wash/System liquid after 28 days.

No modification is introduced in the LIAISON® Murex HIV Ab/Ag HT device or in any other LIAISON® Assay as a part of this change.

Performance Data:

A: Analytical studies

1. Precision Study:

   A panel of six samples (HIV negative, HIV-1M, HIV-1 O, HIV-2 low positive, HIV-2 high positive, and p24 Ag) were tested.
   One lot of LIAISON® Murex HIV Ab/Ag HT was used.
   Samples were tested on (b) (4) LIAISON® XL analyzer connected to (b) (4) LIAISON® diluteX over (b) (4) days, with (b) (4) runs per day, and (b) (4) replicates per run, resulting in (b) (4) replicates per sample. The performance results of the precision study are summarized in Table 2.

Table 2: Analysis of precision study results

Sample	Mean S/CO	Within Run (Repeatability)		Between Run		Between Day		Intermediate Precision	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
HIV NEG	0.739	0.03	3.69%	0.02	3.36%	0.04	5.36%	0.05	7.32%
HIV-P24	3.27	0.06	1.88%	0.04	1.25%	0.05	1.55%	0.09	2.74%
HIV2 LP	1.26	0.04	3.00%	0.00	0.00%	0.03	2.60%	0.05	3.87%
HIV2-HP	2.27	0.06	2.65%	0.03	1.50%	0.05	2.12%	0.08	3.71%
HIV-1M	2.16	0.06	2.76%	0.04	1.80%	0.10	4.78%	0.13	5.81%
HIV-1O	2.10	0.04	2.13%	0.03	1.65%	0.03	1.53%	0.07	3.10%

These results support acceptable precision of the LIAISON® Murex HIV Ab/Ag HT assay run on LIAISON® XL analyzer connected to LIAISON® diluteX.

2. Reproducibility Study

This study was performed at (b) (4) site by testing the LIAISON® Murex HIV Ab/Ag HT assay with (b) (4) LIAISON® XL analyzers, each connected to LIAISON® diluteX. (b) (4) kit lot of LIAISON® Murex HIV Ab/Ag HT and LIAISON® Murex HIV Ab/Ag HT Control kit lot was used.
A panel of six samples (HIV negative, HIV-1M, HIV-1 O, HIV-2 low positive, HIV-2 high positive, and p24 Ag) were tested.
Each panel member was tested over (b) (4) days, on (b) (4) analyzers, with (b) (4) run per day and in (b) (4) replicates per run, resulting in a total of (b) (4) replicates per sample. The test results of the reproducibility study are summarized in Table 3.

Table 3: Analysis of Reproducibility Study results

Sample	Mean (S/CO)	Intra-Run		Between Day		Within Instrument		Between Instrument		Overall Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
HIV-NEG	0.616	0.0224	3.63%	0.0252	4.09%	0.0337	5.47%	0.0109	1.76%	0.0354	5.75%
HIV-P24	2.22	0.0692	3.11%	0.0383	1.72%	0.0790	3.55%	0.0000	0.00%	0.0790	3.55%
HIV-2LP	0.979	0.0293	2.99%	0.0282	2.88%	0.0407	4.15%	0.0000	0.00%	0.0407	4.15%
HIV-2HP	2.70	0.0818	3.03%	0.0534	1.98%	0.0977	3.62%	0.0290	1.07%	0.102	3.77%
HIV-1M	1.76	0.0669	3.80%	0.0843	4.79%	0.108	6.11%	0.0000	0.00%	0.108	6.11%
HIV-1O	1.65	0.0559	3.38%	0.0367	2.22%	0.0669	4.05%	0.0000	0.00%	0.0669	4.05%

These results support acceptable reproducibility of the LIAISON® Murex HIV Ab/Ag HT assay run on LIAISON® XL analyzer connected to LIAISON® diluteX.

3. Method Comparison with Predicate Device:

This study was conducted to compare the performance of the LIAISON® Murex HIV Ab/Ag HT assay run on the LIAISON® XL analyzer connected to LIAISON® diluteX (candidate) and the assay run on LIAISON® XL analyzer in standard configuration (predicate).
A total of 115 serum and plasma samples (HIV negative, HIV-1, HIV-2, HIV-2, and p24 Ag positive) covering the assay range were used.
One lot of LIAISON® Murex HIV Ab/Ag HT was used.
One lot of LIAISON® Murex Control HIV Ab/Ag HT was used.

Overall agreement was 110/115 (95.6) with five samples being classified as discordant. The test results are summarized in Table 4.
Three of five discordant samples were close to the assay cutoff (1.00 S/CO) with concentrations ranging from 0.98 to 1.11 S/CO on the LIAISON® XL in standard configuration and from 0.75 to 1.07 on the LIAISON® XL connected to diluteX. Positive

percent agreement (PPA) and negative percent agreement (NPA) are presented in Table 5. A summary of discordant results is presented in Table 6.

Table 4: Overall method agreement

		Without DiluteX		Total
		Negative	Positive	
With DiluteX	Negative	50	4	54
	Positive	1	60	61
Total		51	64	115

Table 5: Positive percent agreement and negative percent agreement estimates

	Absolute	Point estimate %	Two-sided 95% CI
PPA	60/64	93.8	84.7 - 98.20
NPA	50/51	98	89.5 - 99.80

Table 6: Summary of discordant test results

	Without diluteX		With diluteX	
Sample ID	S/CO	Results	S/CO	Results
HIVHT-03-B05	0.981	Negative	1.07	Positive
15621-500K	1.03	Positive	0.989	Negative
13159-20K	1.04	Positive	0.855	Negative
15813-144K	1.10	Positive	0.750	Negative
15765-200K	1.11	Positive	0.993	Negative

To demonstrate the equivalence of LIAISON® Murex HIV Ab/Ag HT assay performance when connected to diluteX and in standard configuration, data derived from the method comparison study was further assessed to evaluate regression between the two configurations. For this purpose, Deming Regression analysis was performed with all samples (Figure 1) as well as with samples close to the cutoff, S/CO of 0.5 – 3.50 (Figure 2). When the entire range of the tested samples is included, the slope is 0.83 and the r^2 is 0.9957. When the samples with S/CO of 0.5 through 3.50 are plotted, the slope is 0.976 and the r^2 is 0.9402.

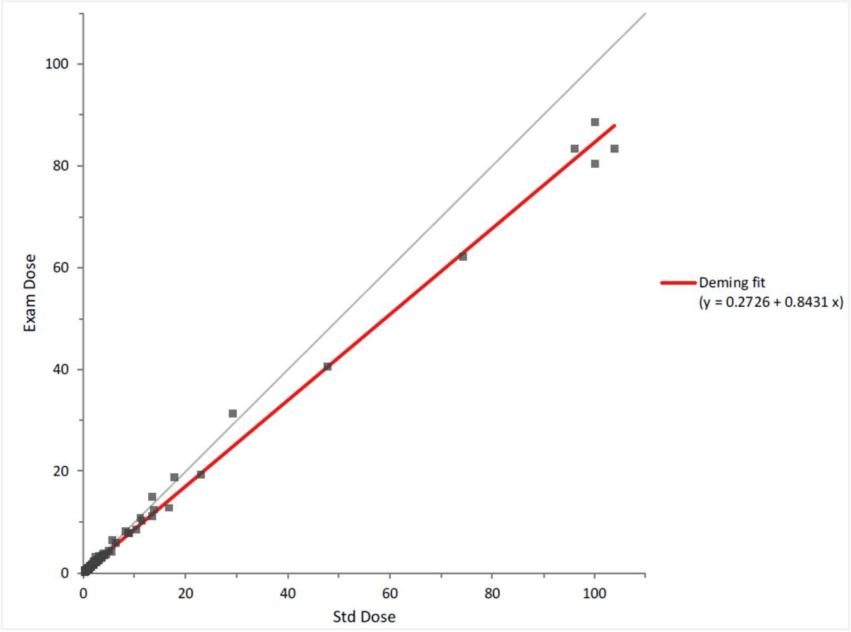

Figure 1: Scatter Plot of the regression analysis from all samples included in the method comparison study with the LIAISON® Murex HIV Ab/Ag HT assay.

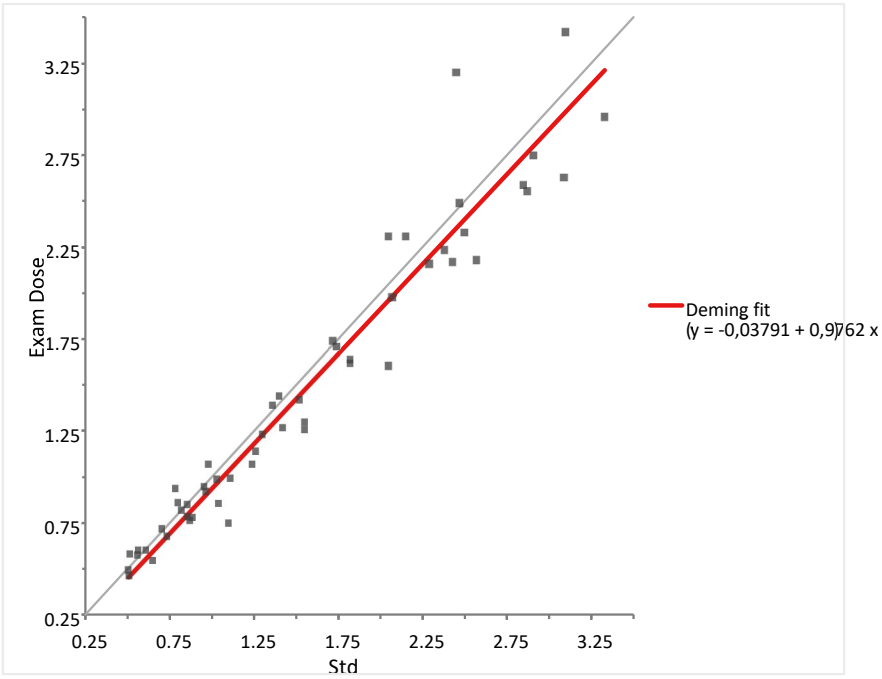

Figure 2: Scatter Plot of the regression analysis from samples with S/CO of 0.5 – 3.5 included in the method comparison study with the LIAISON® Murex HIV Ab/Ag HT assay.

This study demonstrates that the performance of LIAISON® Murex HIV Ab/Ag HT assay is comparable when run on the LIAISON® XL analyzer with or without the LIAISON® diluteX accessory.

4. Carry-Over:

A carryover study was split into two stages as follows:
Stage A: To establish a robust mean signal of the negative sample, five aliquots of the negative sample were tested, twice in duplicates, in two separate runs.
Stage B: To determine any possible contamination from one cuvette to the next, single replicates of the negative sample were tested alternating with a single replicate of the high positive sample. This stage was performed in five separate runs.
One sample with high level of analyte (S/CO above 200) and one negative sample were used.
One lot of LIAISON® Murex HIV Ab/Ag HT and one lot of LIAISON® Murex Control HIV Ab/Ag HT were used.
Samples were tested on three LIAISON® XL analyzers connected to LIAISON® diluteX.
The summary of the carryover study results is presented in Table 7 below. All positive samples were positive.

Table 7: Results of Analyte carryover study

	Analyzer 1		**Analyzer 2**		**Analyzer 3**	
	Stage A	**Stage B**	**Stage A**	**Stage B**	**Stage A**	**Stage B**
#Positive results	0	0	0	0	0	0
%Positive results (in negative samples)	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
#Negative results	40	25	40	25	40	25
%Negative results	100%	100%	100%	100%	100%	100%

The percentage of negative results observed was 100% for both stage A and B, and therefore, no carryover was observed. This study demonstrates that there is no observed cross-contamination or analyte carryover when LIAISON® Murex HIV Ab/Ag HT assay is run on the LIAISON® XL analyzer connected to the LIAISON® diluteX accessory.

B. Other Supportive Instrument Performance Characteristics Data:

Stability testing of 10X LIAISON® Wash/Sys liquid in the diluteX tank:
The purpose of this study was to evaluate whether the 10X LIAISON® Wash/Sys liquid is stable when stored on the diluteX accessory. Although the composition of the 10X LIAISON® Wash/Sys liquid has not changed from that approved under the original PMA (BP190437), it is feasible that the stability of the liquid may be affected by the following factors:

1. Leaching of chemicals from the storage container of diluteX
2. Exposure to air in void spaces during storage inside diluteX
3. Potential microbiological contamination due to new pipelines connection between diluteX and the XL Analyzers.

Verification of the chemical stability (monitored by measuring the concentration of peroxide and pH) and microbial contamination were monitored every seven days over a period of 35 days. At all tested time points, peroxide concentration, pH and microbial load were within the acceptable range for all three reagent lots of Wash/System liquid (10X).

The 10X Wash/Sys liquid is required to wash the magnetic particles used in LIAISON® immunoassays and this reagent is common across all of the assays run on the LIAISON® XL analyzers including LIAISON® Murex HIV Ab/Ag HT assay. To assess the stability of the Wash/System liquid within the diluteX container, two FDA-approved representative assays were selected for validation testing. The LIAISON® Murex HBc IgM assay was chosen as an antibody-based assay while the LIAISON® Murex HBsAg Qual assay was selected as an antigen-based assay. The testing was performed on days 28 (T1) and 29 (T2). All samples were tested on one LIAISON® XL analyzer in its standard configuration and connected to a LIAISON® dilute accessory. The agreement of test results was estimated in both conditions for each assay.

1. LIAISON® Murex HBc IgM: A total of 104 samples were tested; on day 28 there were no discordant results observed, while on day 29, one discordant test result was observed. The PPA and NPA are summarized in Table 8.

Table 8: Agreement of test results with LIAISON® Murex HBc IgM assay in standard and diluteX-connected configuration

Type of agreements	Results
Positive Agreement T1	100%
Negative Agreement T1	100%
Positive Agreement T2	100%
Negative Agreement T2	97.9%

2. LIAISON® Murex HBsAg Qual: A total of 103 samples were tested; on day 28, there were three discordant results observed, while on day 29, there were no discordant test results. The positive and negative percent agreements are summarized in Table 9.

Table 9: Agreement of test results with LIAISON® Murex HBsAg Qual assay in standard and diluteX-connected configuration

Type of agreements	Results
Positive Agreement T1	97.9%
Negative Agreement T1	96.4%
Positive Agreement T2	100%
Negative Agreement T2	100%

Considering that the discordant test results were close to the cutoff, the stability claim for 10X LIAISON® Wash/System liquid inside the diluteX storage tank for 28 days is acceptable.

Conclusion

The results of the analytical and method comparison studies demonstrate that the LIAISON® Murex HIV Ab/Ag HT assay for use on the LIAISON® XL analyzer connected to LIAISON® diluteX is as safe, as effective, and performs as well as the predicate device.