Updated 510(k) Summary: BK231025 (Aptima HIV-1 Quant Dx Assay)

Contact Details

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Device Name

Device Trade Name: Aptima HIV-1 Quant Dx Assay

Common Name: HIV-1 RNA assay

Classification Name: Human immunodeficiency virus (HIV) viral load monitoring test

Regulation Number: 866.3958

Product Code: QUM

Legally Marketed Predicate Devices

Predicate #: BP150318

Predicate Trade Name (Primary Predicate is listed first): Aptima HIV-1 Quant Assay

Product Code: QUM

Device Description Summary

The Aptima® HIV-1 Quant Dx assay is an in vitro nucleic acid amplification test (NAAT) for the detection and quantitation of human immunodeficiency virus type 1 (HIV-1) on the fully automated Panther® system and Panther Fusion® system. It is intended to be used as an aid in diagnosis for HIV-1 infection using appropriate HIV testing algorithms. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 is indicative of acute or primary infection. The test is to be performed by laboratory personnel trained to perform the test in a hospital or laboratory setting.

Intended Use/Indications for Use

The Aptima® HIV-1 Quant Dx assay is an in vitro nucleic acid amplification test (NAAT) for the detection and quantitation of human immunodeficiency virus type 1 (HIV-1) on the fully automated Panther® system and Panther Fusion® system. It is intended to be used as an aid in diagnosis for HIV-1 infection using appropriate HIV testing algorithms. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 is indicative of acute or primary infection.

The Aptima HIV-1 Quant Dx assay may also be used as a supplemental test, when it is reactive, to confirm HIV-1 infection in an individual whose plasma or serum specimen is reactive with an approved assay with an indication as an aid in the diagnosis of HIV-1 infection.

The Aptima HIV-1 Quant Dx assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels. The Aptima HIV-1 Quant Dx assay quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/ mL. One international unit is equivalent to 0.35 copies of HIV-1 RNA for the 3rd HIV-1 WHO International Standard (subtype B, NIBSC code: 10/152).

This assay is not intended to be used as a donor screening test for HIV-1. Performance of this test has not been evaluated for use in pregnant women or in a pediatric population.

Indications for Use Comparison

The indications for use for the device are the same as the predicate device.

Technological Comparison

The device has the same technological characteristics as the predicate device(s) identified above. The design, material, chemical composition, principle of operation and energy source are identical. Similarities and differences between the predicate and subject devices are listed below in Tables 1 and 2.

Table 1: Comparison of Similarities Between Predicate Device and Subject Device

Item	**Predicate Device:** **Aptima HIV-1 Quant Dx assay (BP150318)**	**Subject Device:** **Aptima HIV-1 Quant Dx assay**
Technology Principle of Operation	Target Capture (TC), Transcription-Mediated Amplification (TMA)	Same
Platform	Automated Panther System and Panther Fusion System	Same
Assay Targets	HIV-1 RNA	Same
Assay Results	Qualitative & quantitative	Same
Function	Detection of RNA from HIV-1	Same
Intended Use	The Aptima® HIV-1 Quant Dx assay is an in vitro nucleic acid amplification test (NAAT) for the detection and quantitation of human immunodeficiency virus type 1 (HIV-1) on the fully automated Panther® system and Panther Fusion® system. It is intended to be used as an aid in diagnosis for HIV-1 infection using appropriate HIV testing algorithms. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 is indicative of acute or primary infection. The Aptima HIV-1 Quant Dx assay may also be used as a supplemental test, when it is reactive, to confirm HIV-1 infection in an individual whose plasma or serum specimen is reactive with an approved assay with an indication as an aid in the diagnosis of HIV-1 infection.	Same

Item	Predicate Device: Aptima HIV-1 Quant Dx assay (BP150318)	Subject Device: Aptima HIV-1 Quant Dx assay
	The Aptima HIV-1 Quant Dx assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels. The Aptima HIV-1 Quant Dx assay quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/ mL. One international unit is equivalent to 0.35 copies of HIV-1 RNA for the 3rd HIV-1 WHO International Standard (subtype B, NIBSC code: 10/152). This assay is not intended to be used as a donor screening test for HIV-1. Performance of this test has not been evaluated for use in pregnant women or in a pediatric population.	

Table 2: Comparison of Differences Between Predicate Device and Subject Device

Item	Predicate Device: Aptima HIV-1 Quant Dx assay (BP150318)	Subject Device: Aptima HIV-1 Quant Dx assay
LTR software improvement	N/A	1. Add a logic in the RTF1 (pol) channel that will increase the reported pol positivity: that if the pol RFU range result is above 5000, the ratio cut-off for positivity is not applied. 2. Add a Validity check in the RTF3 (LTR) channel that: If the specimen GIC Ttime is greater than the Average GIC Ttime of the Kit Calibrator in the run + 2 minutes, the software will invalidate the reported LTR result with a calculated concentration

Item	Predicate Device: Aptima HIV-1 Quant Dx assay (BP150318)	Subject Device: Aptima HIV-1 Quant Dx assay
		between 50 c/mL and 10,000 c/mL. 3. Add another logic in the RTF3 (LTR) channel to invalidate the samples with an abnormal fluorescence curve in the LTR channel or the "LTR bump." The software will invalidate the samples that have a reported LTR concentration of greater than 5,000 c/mL with less than LTR RFU Range of 1250.
Reagents can be loaded onto the Panther system or Panther Fusion system	5 times	8 times
Results impacted by faulty or flickering LED in Panther instrument or Panther Fusion instrument	Read as normal, potentially producing incorrect results	Marked as invalid results

Non-Clinical and/or Clinical Tests Summary & Conclusions

Analytical Study:

Results of the reanalysis of line data, from the verification and validation studies in the original Aptima HIV Quant submission (BP150318), with the new logics implemented in the parameters for the RFT1 (pol) and RTF3(LTR) channels, met the original acceptance criteria. There was no change in the acceptance criteria of any of these instrument performance studies when the data was reanalyzed with the new parameters. Field data were analyzed to support the change in new estimated background limits. Process control improvement for flickering LED (high background) demonstrated improved fault detection.

Clinical Study:

No new clinical testing was performed. The original clinical validation line data in BP150318 was reanalyzed with the new parameters. There were no clinically relevant changes which would affect study results or assay claims.

Method Comparison:

A new method comparison study was performed using HIV-positive samples, and regression analysis was conducted separately across the entire assay range and around the cut-off. The study showed no difference in quantitative results between the current Aptima HIV-1 Quant Dx Panther Assay Sequence File and after reprocessing with the proposed new parameters/logics implemented in the Aptima HIV-1 Quant Dx Assay Sequence File version 6.0.5.2. The proposed new parameters/logics did not have an impact on the low out-of-range specimens (<30 c/mL or <1.48 log10 c/mL) which remained detectable (but not quantitated). Due to the logic in the RTF1 (Pol) channel which removes the Pol ratio cut-off for samples with a Pol RFU of >5000, the new sequence file containing the updated parameters, was able to detect one low positive specimen that was not detected by the current Aptima HIV-1 assay sequence file. This logic also detected pol positivity (with a concentration of <1 c/mL) on one low positive specimen that was positive for LTR target but

negative for pol by the current Aptima HIV-1 assay sequence file. All true/known negative specimens remain "Not Detected" or "Non-Reactive" in the updated Assay Sequence File version 6.0.5.2. Results are summarized in Table 3 below.

Table 3: Aptima HIV-1 Assay Sequence File version 5.3.5.1 vs 6.0.5.2 Summary Results

Current (v5.3.5.1) Sequence File		New (v6.0.5.2) Sequence File		OLD Seq File (Channel)	New SeqFile Channel	Total Count
Reactive	Not Quantified	Reactive	Not Quantified	LTR	pol	1
				pol	pol	31
	Quantified		Quantified	pol	pol	156
Non-reactive	Not Detected	Non-reactive	Not Detected	Not Detected	Not Detected	21
		Reactive	Not Quantified		pol	1
Grand Total						210

On-Board Stability:

Additional reagent cycling on and off board the Panther instrument was conducted using the protocol and panel composition from the original PMA (BP150318), and the HIV Quant Dx Assay was able to successfully complete 10 loads with acceptable assay performance and reagent volume. This supports the proposed change of 5 reagent cycle loads to 8 reagent cycle loads.

Substantial Equivalence Comparison Conclusion:

The results of non-clinical analytical and clinical performance studies demonstrate that the Aptima HIV-1 Quant Dx Assay is as safe, as effective, and performs as well as the predicate device.