November 5, 2022

DiaSorin Molecular LLC
Sharon Young
Principal Regulatory Affairs Specialist
11331 Valley View Street
Cypress, California 90630

Re: K202755
Trade/Device Name: Simplexa Congenital CMV Direct and Simplexa Congenital CMV Positive Control Pack
Regulation Number: 21 CFR 866.3181
Regulation Name: Cytomegalovirus Nucleic Acid Detection Device For Congenital Cytomegalovirus Infection
Regulatory Class: Class II
Product Code: QDZ
Dated: September 17, 2020
Received: September 21, 2020

Dear Sharon Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maria I. Garcia -S

Maria Garcia, Ph.D.
Assistant Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202755

Device Name
Simplexa™ Congenital CMV Direct and Simplexa™ Congenital CMV Positive Control Pack

Indications for Use *(Describe)*
Simplexa™ Congenital CMV Direct Catalog Number MOL2250
The DiaSorin Molecular Simplexa™ Congenital CMV Direct is a real-time PCR assay intended for use on the LIAISON® MDX instrument for the in vitro qualitative detection of cytomegalovirus (CMV) from saliva swabs and urine from infants less than 21 days of age. Positive results from saliva are presumptive and should be confirmed with urine. The results of the Simplexa™ Congenital CMV Direct assay should be used in conjunction with the results of other clinical findings as an aid in the diagnosis of congenital CMV infection.

This test has not been cleared for screening of blood or blood products for the presence of CMV or for use with samples other than urine and saliva swabs

Simplexa™ Congenital CMV Positive Control Pack Catalog Number MOL2260 DiaSorin Molecular's Simplexa™ Congenital CMV Positive Control Pack is intended to be used as a control with the Simplexa Congenital CMV Direct kit for use on the LIAISON MDX instrument. This control is not intended for use with other assays or systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Applicant	DiaSorin Molecular LLC. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Tara Viviani, RAC Sr. Directory Molecular Regulatory Affairs Tel. 562.240.6680 Tara.Viviani@DiaSorin.com
Summary Date	November 2, 2022
Proprietary Name	Simplexa™ Congenital CMV Direct and Simplexa™ Congenital CMV Positive Control Pack
US Product Codes/Names and Regulation Numbers	QDZ – Cytomegalovirus nucleic acid detection device for congenital cytomegalovirus infection 21 CFR § 866.3281 OOI - Instrumentation for clinical multiplex test systems 21 CFR § 862.2570
Classification	Class II
Predicate Devices	Alethia® CMV Assay Test System DEN180040 (for saliva swab). Currently, there is not a predicate device for urine as a compatible specimen type.

Intended Use

Simplexa™ Congenital CMV Direct REF MOL2255

The DiaSorin Molecular Simplexa™ Congenital CMV Direct is a real-time PCR assay intended for use on the LIAISON® MDX instrument for the in vitro qualitative detection of cytomegalovirus (CMV) from saliva swabs and urine from infants less than 21 days of age. Positive results from saliva are presumptive and should be confirmed with urine. The results of the Simplexa™ Congenital CMV Direct assay should be used in conjunction with the results of other clinical findings as an aid in the diagnosis of congenital CMV infection.

This test has not been cleared for screening of blood or blood products for the presence of CMV or for use with samples other than urine and saliva swabs.

Simplexa™ Congenital CMVPositive Control Pack REF MOL2265

DiaSorin Molecular's Simplexa™ Congenital CMV Positive Control Pack is intended to be used as a control with the Simplexa™ Congenital CMV Direct kit for use on the LIAISON® MDX instrument. This control is not intended for use with other assays or systems.

Device Description

The Simplexa™ Congenital CMV Direct assay is a real-time PCR system that enables the direct amplification and detection of CMV DNA from either saliva swab or urine specimens without nucleic acid extraction. The system consists of the Simplexa™ Congenital CMV Direct Reaction Mix, the LIAISON® MDX (with LIAISON® MDX Studio Software), the Direct Amplification Disc (DAD) and associated accessories.

In the Simplexa™ Congenital CMV Direct assay, bi-functional fluorescent probe-primers are used together with corresponding reverse primers to amplify CMV DNA. A well-conserved region of the CMV UL83 gene is targeted to identify CMV DNA. An internal control is used to detect PCR failure and/or inhibition.

Simplexa™ Congenital CMV Direct REF MOL2255

Component Name	REF	EC Symbol on Label		Abbreviated Name	Cap Color	Number of Vials	Reactions per Vial/Kit	Volume per Vial
Simplexa™ Congenital CMV Direct Reaction Mix	MOL2256	REAG	C	RM	White	24	1/24	50 µL

Simplexa™ Congenital CMV Direct Components and Descriptions

Kit Component	Contents				
Simplexa™ Congenital CMV Direct Reaction Mix (RM)	DNA polymerase, buffer, dNTPs, template DNA (Internal Control), dye-labeled fluorescent probes and primers specific for detection of CMV and for the DNA Internal Control.				
	Target	**Probe Fluorophore (Dye)**	**Excitation (nm)**	**Emission (nm)**	**Targeted Gene**
	CMV	FAM	495	520	UL83 gene
	Internal Control RNA (IC)	Q670	644	670	N/A
Simplexa™ Congenital CMV Direct Barcode Card	Assay specific parameters and lot information				

Simplexa™ Congenital CMV Positive Control Pack REF MOL2265
Component and Description

Component Name	REF	Description	Cap Color	Number of Vial	Reactions per Vial/Kits	Volume per Vial
Simplexa™ Congenital CMV Direct Positive Control	MOL2256	Inactivated CMV	Red	10	1/10	50µL

Materials Supplied Separately

Direct Amplification Disc Kit (REF MOL1455) Direct Amplification Discs for use on the LIAISON® MDX

Comparison to Predicate Device

Comparison to Predicate Device	Predicate Device: Alethia CMV Assay Test System (DEN180040)	Candidate Device: Simplexa™ Congenital CMV Direct and Simplexa™ Congenital CMV Positive Control Pack
Product Code	QDZ	Same
Regulation Number and Description	21 CFR § 866.3381 – Cytomegalovirus nucleic acid detection device for congenital cytomegalovirus infection.	Same
Organism Detected	cytomegalovirus	Same
Measurand	gene	A well-conserved region of the CMV UL83
Intended Use Kit	The Alethia CMV Assay Test System includes separately provided test kits for the Alethia CMV DNA Amplification Assay and the Alethia CMV External Control Reagents. The Alethia CMV DNA Amplification Assay, performed on the Alethia instrument, is a qualitative, in vitro diagnostic test system for the direct detection of Cytomegalovirus (CMV) DNA in saliva samples from neonates younger than 21 days of age. The test is used as an aid in the diagnosis of congenital CMV infection. The results of this test should be used in conjunction with the results of other clinical findings. Flocked swabs should be used to collect saliva from neonates. The swab can be collected dry, without viral transport media (VTM), or placed in no more than 1 mL VTM. The Alethia CMV External Control Reagents are used as part of a routine quality control program to aid the user in detection of unexpected conditions that may lead to test errors. The external controls are intended for use with the Alethia CMV DNA Amplification Assay; the controls are not intended for use with other assays or systems.	The DiaSorin Molecular Simplexa™ Congenital CMV Direct is a real-time PCR intended for use on the LIAISON MDX instrument for the *in vitro* qualitative detection of cytomegalovirus (CMV) from saliva swabs and urine from infants less than 21 days of age. The Simplexa™ Congenital CMV Direct is an aid in the diagnosis of congenital CMV infection.
Intended Use Control Pack	The Alethia CMV Assay Test System includes separately provided test kits for the Alethia CMV DNA Amplification Assay and the Alethia CMV External Control Reagents. The Alethia CMV External Control Reagents are used as part of a routine quality control program to aid the user in detection of unexpected conditions that may lead to test errors. The external controls are intended for use with the Alethia CMV DNA Amplification Assay; the controls are not intended for use with other assays or systems.	The Simplexa™ Congenital CMV Positive Control Pack is intended to be used as a control with the Simplexa™ Congenital CMV Direct kit. This control is not intended for use with other assays or systems.

Comparison to Predicate Device	Predicate Device: Alethia CMV Assay Test System (DEN180040)	Candidate Device: Simplexa™ Congenital CMV Direct and Simplexa™ Congenital CMV Positive Control Pack
Automated System (Sample to Answer)	Yes	Same
Instrumentation	Alethia™ Instrument; Meridian Bioscience, Inc.	LIAISON® MDX
Sample Types/Media Type	Dry flocked saliva swab or saliva swab in 1 mL VTM from infants < 21 days old.	Saliva swab in BD Universal Viral Transport (UVT), Copan UTM® (1mL or 3mL), Remel M4RT®, M4®, and M6® transport and urine from infants less than 21 days old.

CLINICAL AGREEMENT

The performance of the Simplexa™ Congenital CMV Direct assay was established in a clinical study that included two (2) cohorts based on sample status. Specifically, prospective and retrospective (pre-selected positive and negative samples based on routine laboratory results) samples from infants less than twenty-one (21) days of age, were tested in the clinical agreement study.

Retrospective Study

A total of 346 retrospective specimens were collected during the clinical study. Specimens were enrolled, aliquoted and shipped to a central site where they were distributed for Simplexa™ Congenital CMV Direct testing at three (3) laboratories. One (1) central laboratory performed both comparator PCR/bi-directional sequencing assays for the two (2) part Composite Reference Method (CRM). The Composite Reference Method (CRM) utilized two (2) validated PCR followed by bi-directional sequencing assays. A sample had a final sequencing result of 'Detected' if one or both sequencing results were 'Detected'. Conversely a sample had a final sequencing result of 'Not Detected' if both results were 'Not Detected'.

Of the 346 specimens tested, 170 results were generated for saliva swab specimens and 173 results were generated for urine specimens. The results are presented in Tables 3a and 3b.

The saliva swab study included 173 specimens in the analysis. Three (3) specimens were removed from analysis. The three (3) samples yielded an indeterminate final result with the Composite Reference Method (CRM) CMV-2 PCR/Bi-directional sequencing assay preventing the algorithm from producing a result for use as a comparator.

Table 3a. Simplexa™ Congenital CMV Direct Clinical Agreement – Saliva Swab (Retrospective)

Clinical Agreement				PPA	NPA
Simplexa™ Congenital CMV Direct Results	Composite Reference Method (CRM)				
	Detected	Not Detected	Total		
Detected	53	0	53	**100.0%** (53/53) 95% CI: 93% - 100%	**100.0%** (117/117) 95% CI: 97% - 100%
Not Detected	0	117	117		
Total	53	117	170		

PPA = Positive Percent Agreement, NPA = Negative Percent Agreement. 95% CI = 95% Confidence Interval
The 95% confidence intervals (CI) were calculated following the Wilson Score method.

Table 3b. Simplexa™ Congenital CMV Direct Clinical Agreement – Urine (Retrospective)

Clinical Agreement				PPA	NPA
Simplexa™ Congenital CMV Direct Results	Composite Reference Method (CRM)				
	Detected	Not Detected	Total		
Detected	49	2[a]	51	**100.0%** (49/49) 95% CI: 93% - 100%	**98.4%** (122/124) 95% CI: 94% - 100%
Not Detected	0	122	122		
Total	49	124	173		

[a] Two (2) urine samples were positive by routine methodology.
PPA = Positive Percent Agreement, NPA = Negative Percent Agreement. 95% CI = 95% Confidence Interval
The 95% confidence intervals (CI) were calculated following the Wilson Score method.

Prospective Study

A total of one thousand eight hundred fifty-nine (1,859) saliva swab specimens and/or one thousand six hundred fifty-six (1,656) urine specimens were prospectively collected as frozen and/or fresh specimens. Of these collected specimens, six (6) saliva swab and thirty-two (32) urine specimens were deemed ineligible and removed from analysis. Specimens were collected from ten (10) collection sites across the USA and two (2) collection sites outside the USA. Testing was performed at six (6) testing sites located in the USA. One (1) central laboratory performed both comparator PCR/bi-directional sequencing assays for the two (2) part Composite Reference Method (CRM).

The Composite Reference Method (CRM) utilized two (2) validated PCR followed by bi-directional sequencing assays. A sample had a final sequencing result of 'Detected' if one or both sequencing results were 'Detected'. Conversely a sample had a final sequencing result of 'Not Detected' if both results were 'Not Detected'.

Prospective clinical agreement was based on a total of one thousand eight hundred fifty-three (1,853) saliva swab specimens and one thousand six hundred twenty-four (1,624) urine specimens. The results are presented in Tables 4a and 4b.

Table 4a. Simplexa™ Congenital CMV Direct Clinical Agreement – Saliva Swab (Prospective)

Clinical Agreement				PPA	NPA
Simplexa™ Congenital CMV Direct Results	Composite Reference Method (CRM)				
	Detected	Not Detected	Total		
Detected	**16**	**1**	**17**	**94.1%** (16/17) 95% CI: 73% - 99%	**99.9%** (1835/1836) 95% CI: 100% - 100%
Not Detected	**1[a]**	**1835**	**1836**		
Total	**17**	**1836**	**1853**		

[a] One (1) saliva swab specimen was negative by routine methodology.
PPA = Positive Percent Agreement, NPA = Negative Percent Agreement. 95% CI = 95% Confidence Interval
The 95% confidence intervals (CI) were calculated following the Wilson Score method.

Table 4b. Simplexa™ Congenital CMV Direct Clinical Agreement – Urine (Prospective)

Clinical Agreement				PPA	NPA
Simplexa™ Congenital CMV Direct Results	Composite Reference Method (CRM)				
	Detected	Not Detected	Total		
Detected	41	0	41	**95.3%** (41/43) 95% CI: 85% - 99%	**100%** (1581/1581) 95% CI: 100% - 100%
Not Detected	2[a]	1581	1583		
Total	43	1581	1624		

[a] Two (2) urine specimens were negative by routine methodology.
PPA = Positive Percent Agreement, NPA = Negative Percent Agreement. 95% CI = 95% Confidence Interval
The 95% confidence intervals (CI) were calculated following the Wilson Score method.

REPRODUCIBILITY

Reproducibility for the Simplexa™ Congenital CMV Direct assay was evaluated. Three (3) investigative sites assessed the device's inter-site, inter-day and inter/intra-assay reproducibility. Each of the sites tested the Simplexa™ Congenital CMV Direct Positive Control, No Template Control (NTC), a negative urine sample, a negative saliva swab in UTM sample and eight (8) contrived samples spiked into a negative matrix of either saliva swabs in UTM or urine. The eight (8) contrived samples consisted of a low positive (LP) contrived at approximately 3X the limit of detection (LoD) and a medium positive (MP) contrived at approximately 10X LOD for each of the following: CMV strain AD169 in saliva swabs in UTM, CMV strain AD169 in urine, CMV strain Towne in saliva swabs in UTM, and CMV strain Towne in urine. Each contrived sample was prepared by spiking a specific concentration of the strain into CMV negative urine or a CMV negative saliva swab in UTM. The samples were tested in quadruplicate on nine (9) different days. Each site had three (3) operators who each assayed the entire sample panel and Positive Control twice per day, for a total of two (2) sets of data per day on one (1) LIAISON® MDX instrument, per site. The combined results for all sites are presented in Table 5. The results show the reproducibility of the Simplexa™ Congenital CMV Direct % CV ranged between 0.4-1.6%.

Table 5. Simplexa™ Congenital CMV Direct Reproducibility

Sample CMV Strain and Matrix	Site 1		Site 2		Site 3		All Sites	
	Agreement with expected results	Avg. Ct ± SD (%CV)	Agreement with expected results	Avg. Ct ± SD (%CV)	Agreement with expected results	Avg. Ct ± SD (%CV)	Agreement with expected results	Avg. Ct ± SD (%CV)
Saliva Towne_LP	100.0% (36/36)	34.3 ± 0.32 (0.9%)	100.0% (36/36)	34.5 ± 0.26 (0.7%)	100.0% (36/36)	34.3 ± 0.32 (0.9%)	100.0% (108/108)	34.4 ± 0.32 (0.9%)
Saliva Towne_MP	100.0% (36/36)	32.2 ± 0.25 (0.8%)	100.0% (36/36)	32.5 ± 0.21 (0.6%)	100.0% (36/36)	32.2 ± 0.22 (0.7%)	100.0% (108/108)	32.3 ± 0.25 (0.8%)
Saliva AD-169_LP	100.0% (36/36)	33.4 ± 0.34 (1.0%)	100.0% (36/36)	33.8 ± 0.23 (0.7%)	100.0% (36/36)	33.5 ± 0.25 (0.8%)	100.0% (108/108)	33.6 ± 0.32 (1.0%)
Saliva AD-169_MP	100.0% (36/36)	32.2 ± 0.22 (0.7%)	100.0% (36/36)	32.3 ± 0.27 (0.8%)	100.0% (36/36)	32.1 ± 0.15 (0.5%)	100.0% (108/108)	32.2 ± 0.23 (0.7%)
Urine Towne_LP	100.0% (36/36)	33.9 ± 0.51 (1.5%)	100.0% (36/36)	34.0 ± 0.48 (1.4%)	100.0% (36/36)	33.9 ± 0.45 (1.3%)	100.0% (108/108)	34.0 ± 0.48 (1.4%)
Urine Towne_MP	100.0% (36/36)	32.1 ± 0.26 (0.8%)	100.0% (36/36)	32.3 ± 0.26 (0.8%)	100.0% (36/36)	32.1 ± 0.21 (0.7%)	100.0% (108/108)	32.2 ± 0.26 (0.8%)
Urine AD-169_LP	100.0% (36/36)	35.9 ± 0.57 (1.6%)	100.0% (36/36)	36.1 ± 0.59 (1.6%)	97.2% (35/36)	35.9 ± 0.46 (1.3%)	99.1% (107/108)	36.0 ± 0.54 (1.5%)
Urine AD-169_MP	100.0% (36/36)	34.0 ± 0.42 (1.2%)	100.0% (36/36)	34.3 ± 0.37 (1.1%)	100.0% (36/36)	34.0 ± 0.33 (1.0%)	100.0% (108/108)	34.1 ± 0.40 (1.2%)
Saliva_ Negative*	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (108/108)	0.0 ± 0.00 (N/A%)
Urine_ Negative*	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (108/108)	0.0 ± 0.00 (N/A%)
NTC (UTM)	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (36/36)	0.0 ± 0.00 (N/A%)	100.0% (108/108)	0.0 ± 0.00 (N/A%)
PC as is	100.0% (36/36)	29.7 ± 0.14 (0.5%)	100.0% (36/36)	29.9 ± 0.13 (0.4%)	100.0% (36/36)	29.6 ± 0.22 (0.7%)	100.0% (108/108)	29.7 ± 0.20 (0.7%)

LP = Low Positive, MP = Moderate Positive, UTM = Universal Transport Media, NTC = No Template Control, PC = Positive Control, SD = Standard Deviation, %CV = Percent Coefficient of Variation, Ct = Cycle Threshold

*Expected result for these samples is negative.

ANALYTICAL SENSITIVITY/LIMIT OF DETECTION

The limit of detection (LoD) was determined for the Simplexa™ Congenital CMV Direct assay using quantified stocks of three (3) CMV strains (AD169, Towne and Merlin) serially diluted in negative human saliva swab and urine matrices. The LoD was determined to be the lowest concentration that could be detected positive > 95% of the time. The LoD for each matrix is presented in Tables 6a and 6b.

Table 6a. Simplexa™ Congenital CMV Direct Limit of Detection – Saliva Swab

CMV strain	LoD – Saliva in 1mL UTM		LoD – Saliva in 3mL UTM		LoD – Saliva in 3mL M4RT	
	Copies/mL in Saliva	Copies/mL in UTM	Copies/mL in saliva	Copies/mL in UTM	Copies/mL in saliva	Copies/mL in M4RT
AD-169	6,750	500	19,250	500	19,250	500
Towne	6,750	500	19,250	500	19,250	500
CMV strain	**IU/mL in saliva**	**IU/mL in UTM**	**IU/mL in saliva**	**IU/mL in UTM**	**IU/mL in saliva**	**IU/mL in M4RT**
Merlin	6,750	500	19,250	500	19,250	500

Table 6b. Simplexa™ Congenital CMV Direct Limit of Detection – Urine

CMV strain	Copies /mL
AD-169	400 Copies/mL
Towne	800 Copies/mL
CMV strain	**IU/mL**
Merlin	6,400 IU/mL

ANALYTICAL REACTIVITY/CROSS REACTIVITY

Analytical Reactivity

The analytical reactivity of the Simplexa™ Congenital CMV Direct assay was evaluated using different strains/genotypes of CMV that were not used in the determination of the limit of detection (LoD) for the assay. Quantified CMV was spiked at 1x LoD into negative adult saliva swab and negative urine from neonates less than 21 days of age. For the saliva swabs the preparations were spiked onto a flocked swab and transferred to each tube of UTM. The results are presented in Table 7. No genotype 4 (gB4) strains were available for testing. In addition to the strains that were physically tested, *in silico* BLAST analysis demonstrated that the assay should detect at least 327 CMV sequences available in the NCBI database, including the four (4) CMV genotypes gB1, gB2, gB3 and gB4.

Table 7. Simplexa™ Congenital CMV Direct Analytical Reactivity

CMV (gB3) Strain and Matrix	Agreement with Expected Results (#Detected/#Total)
CMV Toledo Strain (Saliva Swab)	100% (10/10)
CMV Toledo Strain (Urine)	100% (10/10)

Cross-Reactivity (Analytical Specificity)

The Simplexa™ Congenital CMV Direct assay's analytical specificity was evaluated by testing the ability of the assay to exclusively identify CMV virus with no cross-reactivity to organisms that are closely related, cause similar clinical symptoms or may be present in saliva swabs and urine. Forty-one (41) potential cross-reactants were spiked into negative saliva swab and 13 potential cross reactants were spiked into negative

urine. The samples were assayed in triplicate. No cross-reactivity was observed. The results are presented in Tables 8a and 8b.

Table 8a. Simplexa™ Congenital CMV Direct Cross-Reactivity (Analytical Specificity) - Saliva Swab

No.	Organism	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
1	*Acinetobacter baumannii*	$1x10^6$ CFU/mL	100.0% (3/3)
2	*Actinomyces odontolyticus*	$1x10^6$ CFU/mL	100.0% (3/3)
3	*Bordetella pertussis*	$1x10^6$ CFU/mL	100.0% (3/3)
4	Coronavirus 229E	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
5	CoxsackievirusA9	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
6	Epstein-Barr Virus	$1x10^5$ IU/mL	100.0% (3/3)
7	Enterovirus 71*	$1x10^4$ $TCID_{50}$/mL	100.0% (3/3)
8	FLU A/ Michigan/45/2015	$1x10^5$ Cps/mL	100.0% (3/3)
9	FLU B/ Phuket/3073/2013	$1x10^5$ Cps/mL	100.0% (3/3)
10	*Fusobacterium nucleatum*	$1x10^6$ CFU/mL	100.0% (3/3)
11	Adenovirus (C1)	$1x10^5$ Cps/mL	100.0% (3/3)
12	*Haemophilus influenza*	$1x10^6$ CFU/mL	100.0% (3/3)
13	*Haemophilus parainfluenzae*	$1x10^6$ CFU/mL	100.0% (3/3)
14	Herpes Simplex Virus 1	$1x10^5$ IU/mL	100.0% (3/3)
15	Human herpesvirus 6A	$1x10^5$ Cps/mL	100.0% (3/3)
16	Human herpesvirus 6B	$1x10^5$ Cps/mL	100.0% (3/3)
17	Human herpesvirus 7	$1x10^5$ Cps/mL	100.0% (3/3)
18	Human herpesvirus 8	$1x10^5$ Cps/mL	100.0% (3/3)
19	Human Genomic DNA	$1x10^6$ Cps/mL	100.0% (3/3)
20	Human metapneumovirus	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
21	*Klebsiella oxytoca*	$1x10^6$ CFU/mL	100.0% (3/3)
22	*Klebsiella pneumoniae*	$1x10^6$ CFU/mL	100.0% (3/3)
23	*Moraxella catarrhalis*	$1x10^6$ CFU/mL	100.0% (3/3)
24	*Mycoplasma pneumoniae*	$1x10^6$ CCU/mL	100.0% (3/3)
25	Parainfluenza virus 1	$1x10^5$ U/mL	100.0% (3/3)
26	Parainfluenza virus 2	$1x10^5$ U/mL	100.0% (3/3)
27	Parainfluenza virus 3	$1x10^5$ U/mL	100.0% (3/3)
28	*Porphyromonas gingivalis*	$1x10^6$ CFU/mL	100.0% (3/3)
29	*Pseudomonas aeruginosa*	$1x10^6$ CFU/mL	100.0% (3/3)
30	Respiratory syncytial virus A	$1x10^5$ IU/mL	100.0% (3/3)
31	Respiratory syncytial virus B	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
32	Rhinovirus	$1x10^5$ U/mL	100.0% (3/3)
33	*Staphylococcus aureus*	$1x10^6$ CFU/mL	100.0% (3/3)
34	*Staphylococcus epidermidis*	$1x10^6$ CFU/mL	100.0% (3/3)
35	*Streptococcus anginosus*	$1x10^6$ CFU/mL	100.0% (3/3)
36	*Streptococcus oralis*	$1x10^6$ CFU/mL	100.0% (3/3)

No.	Organism	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
37	*Streptococcus mitis*	$1x10^6$ CFU/mL	100.0% (3/3)
38	*Streptococcus pneumoniae*	$1x10^6$ CFU/mL	100.0% (3/3)
39	*Streptococcus salivarius*	$1x10^6$ CFU/mL	100.0% (3/3)
40	*Streptococcus sanguinis*	$1x10^6$ CFU/mL	100.0% (3/3)
41	Varicella Zoster Virus	$1x10^5$ Cps/mL	100.0% (3/3)

**Expected result for all organisms is negative.
*Enterovirus 71 was tested at a concentration lower than $1x10^5$ $TCID_{50}$/mL due to the low concentration of the virus stock that was available. *In silico* (BLAST) analysis was also performed. The results of the BLAST analysis showed that no cross-reactivity is expected with this microorganism.

Table 8b. Simplexa™ Congenital CMV Direct Cross-Reactivity (Analytical Specificity) - Urine

No.	Organism	Tested Concentration	% Agreement (# Expected Results/ # Tested)
1	*Candida albicans*	$1x10^6$ CFU/mL	100.0% (3/3)
2	*Enterobacter aerogenes*	$1x10^6$ CFU/mL	100.0% (3/3)
3	*Enterobacter cloacae*	$1x10^6$ CFU/mL	100.0% (3/3)
4	*Enterococcus faecium*	$1x10^6$ CFU/mL	100.0% (3/3)
5	*Enterococcus faecalis*	$1x10^6$ CFU/mL	100.0% (3/3)
6	*Escherichia coli*	$1x10^6$ CFU/mL	100.0% (3/3)
7	Herpes Simplex Virus 2	$1x10^5$ cps/mL	100.0% (3/3)
8	*Lactobacillus acidophilus*	$1x10^6$ CFU/mL	100.0% (3/3)
9	*Morganella morganii*	$1x10^6$ CFU/mL	100.0% (3/3)
10	*Proteus mirabilis*	$1x10^6$ CFU/mL	100.0% (3/3)
11	*Proteus vulgaris*	$1x10^6$ CFU/mL	100.0% (3/3)
12	*Streptococcus agalactiae (GBS)*	$1x10^6$ CFU/mL	100.0% (3/3)
13	Enterovirus 71*	$1x10^4$ $TCID_{50}$/mL	100.0% (3/3)

+Expected result for all organisms is negative.
*Enterovirus 71 was tested at a concentration lower than $1x10^5$ $TCID_{50}$/mL due to the low concentration of the virus stock that was available. *In silico* (BLAST) analysis was also performed. The results of the BLAST analysis showed that no cross-reactivity is expected with this microorganism.

INTERFERENCE

The performance of the Simplexa™ Congenital CMV Direct assay was evaluated with potentially interfering substances that may be present in saliva swabs and urine samples at the concentrations indicated in the table below. A total of 17 potentially interfering substances were tested for saliva swabs and seven (7) potentially interfering substances were tested for urine in a low positive CMV sample at approximately three times the limit of detection (3X LoD) in saliva swab and urine matrices and assayed in triplicate. No interference was observed. The results are presented in Tables 9a and 9b.

Table 9a. Simplexa™ Congenital CMV Direct Interference for saliva swab

No.	Potential Interferent	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
1	Acetylsalicylic acid	AD169	0.65 mg/mL	100.0% (3/3)

No.	Potential Interferent	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
		Towne	0.65 mg/mL	100.0% (3/3)
2	Breast milk	AD169	10% (v/v)	100.0% (3/3)
		Towne	10% (v/v)	100.0% (3/3)
3	Caffeine	AD169	0.06 mg/mL	100.0% (3/3)
		Towne	0.06 mg/mL	100.0% (3/3)
4	Casein	AD169	10 mg/mL	100.0% (3/3)
		Towne	10 mg/mL	100.0% (3/3)
5	Enfamil Poly-vi-sol with Iron	AD169	1.5 mg/mL	100.0% (3/3)
		Towne	1.5 mg/mL	100.0% (3/3)
6	Enfamil™ formula neuro pro®	AD169	10% (v/v)	100.0% (3/3)
		Towne	10% (v/v)	100.0% (3/3)
7	Enfamil™ Tri-Vi-Sol®	AD169	8% (v/v)	100.0% (3/3)
		Towne	8% (v/v)	100.0% (3/3)
8	Gaviscon® (Sodium Alginate)	AD169	1.2 mg/mL	100.0% (3/3)
		Towne	1.2 mg/mL	100.0% (3/3)
9	Infants' Pain & Fever (Acetaminophen)	AD169	0.4 mg/mL	100.0% (3/3)
		Towne	0.2 mg/mL	100.0% (3/3)
10	Infants' Mylicon® Gas Relief (Simethicone)	AD169	6.7 mg/mL	100.0% (3/3)
		Towne	6.7 mg/mL	100.0% (3/3)
11	Little Remedies Saline Drops	AD169	10% (v/v)	100.0% (3/3)
		Towne	10% (v/v)	100.0% (3/3)
12	Motrin Infant Drops (Infants' Ibuprofen)	AD169	0.5 mg/mL	100.0% (3/3)
		Towne	0.5 mg/mL	100.0% (3/3)
13	Mucin	AD169	25 mg/mL	100.0% (3/3)
		Towne	25 mg/mL	100.0% (3/3)
14	Nystatin	AD169	1,727 U/mL	100.0% (3/3)
		Towne	1,727 U/mL	100.0% (3/3)
15	Prednisone	AD169	0.0003 mg/mL	100.0% (3/3)
		Towne	0.0003 mg/mL	100.0% (3/3)
16	White Blood Cell	AD169	10% (v/v)	100.0% (3/3)
		Towne	10% (v/v)	100.0% (3/3)
17	Whole blood	AD169	10% (v/v)	100.0% (3/3)
		Towne	10% (v/v)	100.0% (3/3)

**Expected result for all potential interferents is positive.

Table 9b. Simplexa™ Congenital CMV Direct Interference for urine

No.	Organism	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
1	Baby powder	AD169	10% (w/v)	100% (3/3)

No.	Organism	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
		Towne	10% (w/v)	100% (3/3)
2	Johnson's Baby Oil (Mineral Oil)	AD169	10% (v/v)	100% (3/3)
		Towne	10% (v/v)	100% (3/3)
3	Meconium	AD169	0.5% (w/v)	100% (3/3)
		Towne	1% (w/v)	100% (3/3)
4	Moist Towelettes with Benzalkonium Chloride	AD169	10% (w/v)	100% (3/3)
		Towne	10% (w/v)	100% (3/3)
5	Nystatin	AD169	0.3mg/mL	100% (3/3)
		Towne	0.3mg/mL	100% (3/3)
6	Stool	AD169	2% (w/v)	100% (3/3)
		Towne	2% (w/v)	100% (3/3)
7	Whole blood	AD169	5% (v/v)	100% (3/3)
		Towne	10% (v/v)	100% (3/3)

**Expected result for all potential interferents is positive.

INHIBITION BY OTHER MICROORGANISMS

The Simplexa™ Congenital CMV Direct assay was evaluated by testing the ability to identify CMV virus when other potentially inhibitory organisms are present. A panel of forty-one (41) potentially inhibitory organisms was individually spiked into a pool with a low concentration of CMV at approximately three times the limit of detection (3X LoD) in saliva. Thirteen (13) potentially inhibitory organisms were individually spiked into a pool with a low concentration of CMV at approximately three times the limit of detection (3X LoD) in urine. Potentially inhibiting organisms were tested at the concentrations specified in Tables 10a and 10b. No inhibition by other organisms was observed.

Table 10a Simplexa™ Congenital CMV Direct Microbial Interference – Saliva Swab

No.	Organism	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
1	*Acinetobacter baumannii*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
2	*Actinomyces odontolyticus*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
3	*Bordetella pertussis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
4	Coronavirus 229E	AD169	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
		Towne	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
5	CoxsackievirusA9	AD169	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
		Towne	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
6	Epstein-Barr Virus	AD169	$1x10^5$ IU/mL	100.0% (3/3)
		Towne	$1x10^5$ IU/mL	100.0% (3/3)
7	Enterovirus 71*	AD169	$1x10^4$ $TCID_{50}$/mL	100.0% (3/3)

No.	Organism	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
		Towne	1x10^4 $TCID_{50}$/mL	100.0% (3/3)
8	FLU A/ Michigan/45/2015	AD169	1x10^5 Cps/mL	100.0% (3/3)
		Towne	1x10^5 Cps/mL	100.0% (3/3)
9	FLU B/ Phuket/3073/2013	AD169	1x10^5 Cps/mL	100.0% (3/3)
		Towne	1x10^5 Cps/mL	100.0% (3/3)
10	*Fusobacterium nucleatum*	AD169	1x10^6 CFU/mL	100.0% (3/3)
		Towne	1x10^6 CFU/mL	100.0% (3/3)
11	Adenovirus (C1)	AD169	1x10^5 Cps/mL	100.0% (3/3)
		Towne	1x10^5 Cps/mL	100.0% (3/3)
12	*Haemophilus influenza*	AD169	1x10^6 CFU/mL	100.0% (3/3)
		Towne	1x10^6 CFU/mL	100.0% (3/3)
13	*Haemophilus parainfluenzae*	AD169	1x10^6 CFU/mL	100.0% (3/3)
		Towne	1x10^6 CFU/mL	100.0% (3/3)
14	Herpes Simplex Virus 1	AD169	1x10^5 IU/mL	100.0% (3/3)
		Towne	1x10^5 IU/mL	100.0% (3/3)
15	Human herpesvirus 6A	AD169	1x10^5 Cps/mL	100.0% (3/3)
		Towne	1x10^5 Cps/mL	100.0% (3/3)
16	Human herpesvirus 6B	AD169	1x10^5 Cps/mL	100.0% (3/3)
		Towne	1x10^5 Cps/mL	100.0% (3/3)
17	Human herpesvirus 7	AD169	1x10^5 Cps/mL	100.0% (3/3)
		Towne	1x10^5 Cps/mL	100.0% (3/3)
18	Human herpesvirus 8	AD169	1x10^5 Cps/mL	100.0% (3/3)
		Towne	1x10^5 Cps/mL	100.0% (3/3)
19	Human Genomic DNA	AD169	1x10^6 Cps/mL	100.0% (3/3)
		Towne	1x10^6 Cps/mL	100.0% (3/3)
20	Human metapneumovirus	AD169	1x10^5 $TCID_{50}$/mL	100.0% (3/3)
		Towne	1x10^5 $TCID_{50}$/mL	100.0% (3/3)
21	*Klebsiella oxytoca*	AD169	1x10^6 CFU/mL	100.0% (3/3)
		Towne	1x10^6 CFU/mL	100.0% (3/3)
22	*Klebsiella pneumoniae*	AD169	1x10^6 CFU/mL	100.0% (3/3)
		Towne	1x10^6 CFU/mL	100.0% (3/3)
23	*Moraxella catarrhalis*	AD169	1x10^6 CFU/mL	100.0% (3/3)
		Towne	1x10^6 CFU/mL	100.0% (3/3)
24	*Mycoplasma pneumoniae*	AD169	1x10^6 CCU/mL	100.0% (3/3)
		Towne	1x10^6 CCU/mL	100.0% (3/3)
25	Parainfluenza virus 1	AD169	1x10^5 U/mL	100.0% (3/3)
		Towne	1x10^5 U/mL	100.0% (3/3)
26	Parainfluenza virus 2	AD169	1x10^5 U/mL	100.0% (3/3)
		Towne	1x10^5 U/mL	100.0% (3/3)
27	Parainfluenza virus 3	AD169	1x10^5 U/mL	100.0% (3/3)
		Towne	1x10^5 U/mL	100.0% (3/3)

No.	Organism	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
28	*Porphyromonas gingivalis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
29	*Pseudomonas aeruginosa*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
30	Respiratory syncytial virus A	AD169	$1x10^5$ IU/mL	100.0% (3/3)
		Towne	$1x10^5$ IU/mL	100.0% (3/3)
31	Respiratory syncytial virus B	AD169	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
		Towne	$1x10^5$ $TCID_{50}$/mL	100.0% (3/3)
32	Rhinovirus	AD169	$1x10^5$ U/mL	100.0% (3/3)
		Towne	$1x10^5$ U/mL	100.0% (3/3)
33	*Staphylococcus aureus*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
34	*Staphylococcus epidermidis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
35	*Streptococcus anginosus*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
36	*Streptococcus oralis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
37	*Streptococcus mitis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
38	*Streptococcus pneumoniae*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
39	*Streptococcus salivarius*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
40	*Streptococcus sanguinis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
41	Varicella Zoster Virus	AD169	$1x10^5$ Cps/mL	100.0% (3/3)
		Towne	$1x10^5$ Cps/mL	100.0% (3/3)

**Expected result for all organisms is positive.
* Enterovirus 71 was tested at a concentration lower than the 1x105 TCID50/mL due to the low concentration of the virus stock that was available. *In silico* (BLAST)
analysis was also performed. The results of the BLAST analysis showed that no microbial inhibition is expected with this microorganism.

Table 10b Simplexa™ Congenital CMV Direct Microbial Interference – Urine

No.	Organism	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
1	*Candida albicans*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)

No.	Organism	CMV Strain	Tested Concentration	% Agreement** (# Expected Results/ # Tested)
2	*Enterobacter aerogenes*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
3	*Enterobacter cloacae*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
4	*Enterococcus faecium*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
5	*Enterococcus faecalis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
6	*Escherichia coli* ATCC	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
7	Herpes Simplex Virus 2	AD169	$1x10^5$ Cps/mL	100.0% (3/3)
		Towne	$1x10^5$ Cps/mL	100.0% (3/3)
8	*Lactobacillus acidophilus*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
9	*Morganella morganii*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
10	*Proteus mirabilis*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
11	*Proteus vulgaris*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
12	*Streptococcus agalactiae (GBS)*	AD169	$1x10^6$ CFU/mL	100.0% (3/3)
		Towne	$1x10^6$ CFU/mL	100.0% (3/3)
13	Enterovirus 71*	AD169	$1x10^4$ $TCID_{50}$/mL	100.0% (3/3)
		Towne	$1x10^4$ $TCID_{50}$/mL	100.0% (3/3)

**Expected result for all organisms is positive.

* Enterovirus 71 was tested at a concentration lower than the $1x10_5$ $TCID_{50}$/mL due to the low concentration of the virus stock that was available. *In silico* (BLAST) analysis was also performed. The results of the BLAST analysis showed that no microbial inhibition is expected with this microorganism.

CARRY-OVER CONTAMINATION

Amplification carry-over for the Simplexa™ assays has been assessed. The study was designed by alternately placing high positive and negative samples on each disc. No evidence of carry-over contamination was observed.

The performance of the Simplexa™ Congenital CMV Direct assay was established in a clinical study that included two (2) cohorts based on sample status. Specifically, prospective and retrospective samples from infants less than twenty-one (21) days of age were tested in the clinical agreement study.

EXPECTED VALUES

The prevalence of CMV as determined by the Simplexa™ Congenital CMV Direct assay in a multi-site clinical study with prospectively collected specimens was 1.19% for saliva swabs and 2.59% for urine. Table

8 shows the prevalence of saliva swabs by collection site and Table 9 shows the prevalence of urine by collection site.

Table 8. Prospective Results: Simplexa™ Congenital CMV Direct Expected Values for Saliva Swabs by Collection Site

Site ID	Total Specimens	Simplexa™ Congenital CMV Direct Detected	CMV Prevalence
7	142	0	0.00%
8	16	1	6.25%
9	632	3	0.47%
10	9	0	0.00%
12	14	0	0.00%
13	11	1	9.09%
14	9	0	0.00%
15	10	0	0.00%
18	8	0	0.00%
19	1002	12	1.20%
All	**1853**	**17**	**0.92%**

Table 9. Prospective Results: Simplexa™ Congenital CMV Direct Expected Values for Urine by Collection Site

Site ID	All	Simplexa™ Congenital CMV Direct Detected	CMV Prevalence
5	171	2	1.17%
6	1336	36	2.69%
7	5	0	0.00%
8	47	2	4.26%
10	8	0	0.00%
12	13	0	0.00%
13	11	1	9.09%
14	9	0	0.00%
15	10	0	0.00%
18	11	0	0.00%
19	3	0	0.00%
All	**1624**	**41**	**2.52%**

Conclusion

The analytical and method comparison studies have demonstrated that the Simplexa™ Congenital CMV Direct is Substantially Equivalent to the predicate device (DEN180040).The device labeling is compliant with 21 CFR § 809.10.