Date: September 29, 2023

Dynex Technologies Inc.
Jeff Fisher
Vice President, Quality Assurance & Regulatory Affairs
14340 Sullyfield Circle
Chantilly, Virginia 20151

Re: K212769
Trade/Device Name: DYNEX SmartPLEX MMRV IgG Assay Kit
Regulation Number: 21 CFR 866.3510; Rubella Virus Serological Reagents
Regulation Name: Rubella virus serological reagents
Regulatory Class: Class II
Product Code: OPL
Dated: December 7, 2022
Received: December 7, 2022

Dear Jeff Fisher:

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,

Ryan C. Karsner -S

Digitally signed by Ryan C. Karsner -S
Date: 2023.09.29 07:43:51 -04'00'

Ryan Karsner, MD.
Deputy Assistant Director
Hepatitis and General Viral Infections Branch
Division of Microbiology Devices
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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)*
k212769

Device Name
DYNEX SmartPLEX MMRV IgG Assay Kit

Indications for Use *(Describe)*
The DYNEX SmartPLEX MMRV IgG Assay Kit is a multiplex immunoassay intended for the qualitative detection of IgG antibodies to Measles, Mumps, Rubella, and Varicella-Zoster Virus (VZV) in human serum. The DYNEX SmartPLEX MMRV IgG Assay Kit is intended for use with the DYNEX Multiplier Analyzer.

The DYNEX SmartPLEX MMRV IgG Assay Kit is intended to be used as an aid in the determination of serological status to Measles, Mumps, Rubella, and Varicella-Zoster Virus (VZV) in human serum from adults and pediatrics age above 1 year. This kit is not intended for screening blood or plasma donors.

The performance of this device has not been established for use in neonates, pediatric patients below 1 year of age, and immunocompromised patients, or for use at point of care facilities.

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.

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. Submitter Information

DYNEX Technologies, Inc.
14340 Sullyfield Circle
Chantilly, VA 20151
Phone: 703-803-1243
Fax: 703-803-1441

Establishment Registration Number: 1117676

2. Submission Correspondent:

Jeff Fisher
Vice President, Quality Assurance & Regulatory Affairs
Email: jfisher@dynex.com
Phone: 703-803-1266
Fax: 703-803-1441

3. Date Prepared: June 12, 2023

4. Device Information

Classification Name:	Multiplex immunoassay for Measles virus, Mumps virus, Rubella virus, and Varicella-Zoster virus
Common Name:	DYNEX SmartPLEX MMRV IgG on the Multiplier Analyzer
Product Trade Name:	DYNEX SmartPLEX MMRV IgG Assay Kit
Device Class:	Class II
Classification Panel:	Microbiology
Regulation Number:	866.3510
Product Code:	OPL

5. Legally Marketed Predicate Device Information

Name: BioPlex 2200 MMRV IgG

510(k) Number: k091616

Decision Date: 03/29/2010

This predicate has not been subject to a design-related recall according to the FDA Medical Devices Recall website as of August 23, 2021.

6. Device Description

The DYNEX SmartPLEX MMRV IgG Assay Kit (SmartPLEX MMRV IgG Assay) uses multiplex immunoassay, a methodology that greatly resembles traditional ELISA, while permits simultaneous detection and identification of different antibodies in a single well. The reaction is processed in a 96 well microtiter plate, with six polystyrene beads embedded in each well of the plate. Four (4) different beads are coated with antigens for the detection of IgG antibodies to Measles, Mumps, Rubella and Varicella-Zoster virus in human serum. Two additional beads are included in each reaction well as filler beads. Specimen processing is fully automated on the Multiplier Analyzer.

The Multiplier Analyzer adds the patient serum specimen and reagents to each well of the 96-well plate, after which the mixture is incubated at 37°C with shaking. After a wash cycle, unbound antibodies from the patient's specimen are removed. Anti-human polyclonal IgG antibody conjugated to horseradish peroxidase (HRP) is added after which the mixture is incubated at 37°C with shaking. A second wash step removes excess conjugate, then luminol substrate is added to each well. The amount of antibody captured by the antigen is determined by the chemiluminescence triggered by the attached HRP. Raw data is captured as light photons which are converted into relative light intensity units (RLU).

The Multiplier software analyzes the image and generates a report that details the mean RLU signal for each target bead (MMRV) by test sample. In every assay a calibrator is run. The DYNEX SmartPLEX MMRV IgG Assay Kit is qualitative and produces a result defined as negative (NEG), equivocal (EQV) or positive (POS) for each target analyte. The result is calculated in the Multiplier software by dividing the test sample RLU values by the mean calibrator RLU value to produce an index value for each target.

Interpretation of results of the DYNEX SmartPLEX MMRV IgG Assay Kit:

The results for each of the antibodies are expressed in Index units. For Measles, Mumps, Rubella and VZV antibodies, results with Index values ≤ 0.9 Index are reported as Negative, results between >0.9 and <1.1 Index are reported as Equivocal, and results of ≥ 1.1 Index are reported as positive, as indicated in Table 1 below:

Table 1: Interpretation of Results of the DYNEX SmartPLEX MMRV IgG Assay Kit

Result*	Status	Interpretation**
Index value: ≤0.9	NEG	Negative: No detectable IgG antibodies to Measles, Mumps, Rubella or VZV detected. Such individual is presumed not to have had a previous exposure to MMRV through infection or vaccination
Index value: >0.9 - <1.1	EQV	Equivocal: Samples should be retested, if the result remains equivocal, the samples should be tested on an alternative method
Index value: ≥1.1	POS	Positive: IgG antibodies to Measles, Mumps, Rubella, or VZV detected. This may indicate that the individual was exposed to MMRV through infection or vaccination

*The numeric Index value of the final result is not indicative of the amount of anti-Measles, Mumps, Rubella, or VZV IgG antibodies present.
**Test results should be interpreted in conjunction with the clinical history, epidemiological data and other information available to the attending physician in evaluating the patient

Kit Components
The reagents contained in each SmartKit are sufficient to process 92 serum specimens.

Table 2: DYNEX SmartPLEX MMRV IgG Assay Kit Components

Name	REF #	Description
SmartPLEX MMRV IgG Test Plate	7100010	12 x SmartPLEX beaded MMRV strips in strip holder containing beads coated with antigens to Measles virus, Mumps virus, Rubella virus, and Varicella-zoster virus.
SmartPLEX MMRV IgG Assay Kit Quality Control Certificate	7100011	1 x hard copy of the Quality Control certificate describing the performance characteristics of the assay
SmartPLEX Lot Specific Universal Serial Bus (USB)	7100012	Lot specific calibration adjustment factors for each lot of reagents, Safety Data Sheet (SDS), Panel File, Translated Instructions for Use.
SmartPLEX MMRV IgG Assay Kit Instructions for Use (IFU)	71000IFU	Instructions for Use
SmartPLEX MMRV IgG Assay Kit Cap Organizer	90002140	1x Cap Organizer
SmartPLEX MMRV IgG Assay Kit Overlay with QR Code	90003080	1X color-coded card placed to the top of a reagent rack (SmartKit) to guide the user where to place the reagents.

MMRV Sample Diluent	710004	2 x 60 mL bottles of phosphate buffered saline containing ProClin 300 (0.1%) as a preservative.
Wash Buffer (20x Concentrate)	710008	1 x 55 mL bottle of phosphate buffered saline buffer containing ProClin 300 (0.1%) as a preservative.
MMRV IgG Calibrator	710005	1 x 1.2 mL of diluted human serum containing ProClin 300 (0.1%) and sodium azide (<0.01%) as preservatives.
MMRV IgG Positive Control	710007	1 x 1.2 mL of diluted human serum containing ProClin 300 (0.1%) and sodium azide (<0.01%) as preservatives.
MMRV IgG Negative Control	710006	1 x 1.2 mL of diluted human serum containing ProClin 300 (0.1%) and sodium azide (<0.01%) as preservatives.
MMRV Conjugate	710003	1 x 13 mL of purified peroxidase labelled rabbit anti-human polyclonal IgG antibody containing ProClin 300 (0.1%) as a preservative.
Luminol Substrate A	710001	1 x 9.0 mL of Luminol substrate, buffers, stabilizers.
Luminol Substrate B	710002	1 x 9.0 mL of Hydrogen peroxide

Table 3: Additional Required Materials, Available from DYNEX Technologies

Name	REF #
Multiplier Analyzer	63000
DYNEX Sample Pipette Tips (432/box)	65910
DYNEX Reagent Pipette Tips (432/box)	65920
DYNEX Deep-well dilution strips	62910
Reusable SmartKit Rack	MSK009

Table 4:Additional Required Materials, Not Available from DYNEX Technologies

Name
Distilled or deionized water ASTM Type II or higher
1 L graduated or measuring cylinder
50 mL graduated or measuring cylinder

7. Intended Use

The DYNEX SmartPLEX MMRV IgG Assay Kit is a multiplex immunoassay intended for the qualitative detection of IgG antibodies to Measles, Mumps, Rubella, and Varicella-Zoster virus (VZV) in human serum. The DYNEX SmartPLEX MMRV IgG Assay Kit is intended for use with the DYNEX Multiplier Analyzer.

The DYNEX SmartPLEX MMRV IgG Assay Kit is intended to be used as an aid in the determination of serological status to Measles, Mumps, Rubella, and Varicella-Zoster Virus (VZV) in human serum from adults and pediatrics age above 1 year. This kit is not intended for screening blood or plasma donors.

The performance of this device has not been established for use in neonates, pediatric patients below 1 year of age, and immunocompromised patients, or for use at point of care facilities.

8. Comparison of Characteristics

Table 5 below summarize the similarities and differences between the DYNEX SmartPLEX MMRV IgG Assay Kit and the predicate, BioPlex 2200 MMRV IgG.

Table 5: Comparison of the SmartPLEX MMRV IgG Assay Kit with Predicate

Similarities		
	Predicate Device K091616	**Candidate Device K212769**
Trade Name	**BioPlex 2200 MMRV IgG**	**DYNEX SmartPLEX MMRV IgG Assay Kit**
Intended use	The BioPlex 2200 MMRV IgG kit is a multiplex flow immunoassay intended for the qualitative detection of IgG antibodies to Measles, Mumps, Rubella, and Varicella-zoster virus (VZV) in human serum and EDTA or heparinized plasma. The BioPlex 2200 MMRV IgG kit is intended for use with the Bio-Rad BioPlex 2200 System. This kit is intended as an aid in the determination of serological status to Measles, Mumps, Rubella, and VZV. This kit is not intended for use in screening blood or plasma donors.	The DYNEX SmartPLEX MMRV IgG Assay Kit is a multiplex immunoassay intended for the qualitative detection of IgG antibodies to Measles, Mumps, Rubella, and Varicella-Zoster Virus (VZV) in human serum. The DYNEX SmartPLEX MMRV IgG Assay Kit is intended for use with the DYNEX Multiplier Analyzer. The DYNEX SmartPLEX MMRV IgG Assay Kit is intended to be used as an aid in the determination of serological status to Measles, Mumps, Rubella, and Varicella-Zoster Virus (VZV) in human serum from adults and pediatrics age above 1 year. This kit is not intended for screening blood or plasma donors. The performance of this device has not been established for use in neonates, pediatric patients below 1 year of age, and immunocompromised patients, or for use at point of care facilities.

	The performance of this assay has not been established for use in neonates, pediatrics, and immunocompromised patients, or for use at point of care facilities.	
Reagents	Sample diluent, Wash buffer	Same
Controls	Negative control and Multi-analyte Positive control.	Same
Calibrators	Calibrators	Same
Analyte Detection	Qualitative detection of IgG antibodies to Measles, Mumps, Rubella and Varicella-zoster virus.	Same
Differences		
	Predicate Device K091616	**Candidate Device K212769**
Trade Name	**BioPlex 2200 MMRV IgG**	**DYNEX SmartPLEX MMRV IgG Assay Kit**
Solid Phase	Bead reagent - dyed antigen coated beads	96 well microplate – antigen coated polystyrene beads
Reagents	Conjugate: Murine anti-human IgG/phycoerythrin	Conjugate: Rabbit anti-human IgG conjugated to horseradish peroxidase, chemiluminescent luminol substrate
Sheath Fluid	Sheath fluid is used to suspend bead reagent and introduce into the detector	Not used
Matrices	Serum, EDTA, or Heparinized Plasma	Serum
Signal Detection	Fluorescence measured by spectrophotometer	Chemiluminescence measured by an imaging camera

9. Performance Characteristics

The following performance data were provided in support of the substantial equivalence determination.

A. Distribution of qualitative results for each of the analytes detected by the DYNEX SmartPLEX MMRV IgG Assay Kit.

The distribution of qualitative results for each of the analytes detected by the DYNEX SmartPLEX MMRV IgG Assay Kit were determined by using retrospective human serum specimens (N= 2512). Results, per cohort and sex, are shown in Table 6 below.

Table 6: Distribution of Qualitative Results for Each of the Analytes Detected by the DYNEX SmartPLEX MMRV IgG Assay Kit

Result	Cohort	Sex	Age	N	Positive (%)	Equivocal (%)	Negative (%)
Measles	Overall	Female	1-88	1544	1171 (75.8%)	78 (5.1%)	295 (19.1%)
		Male	1-88	968	753 (77.8%)	41 (4.2%)	174 (18.0%)
	Total			2512	1924 (76.6%)	119 (4.7%)	469 (18.7%)
	Pediatric	Female	1-21	134	95 (70.9%)	4 (3.%)	35 (26.1%)
		Male	1-21	202	155 (76.7%)	8 (4.0%)	39 (19.3%)
	Total			336	250 (74.4%)	12 (3.6%)	74 (22.0%)
	Adult	Female	22-88	910	688 (75.6%)	39 (4.3%)	183 (20.1%)
		Male	22-88	766	598 (78.1%)	33 (4.3%)	135 (17.6%)
	Total			1676	1286 (76.7%)	72 (4.3%)	318 (19.0%)
	Pregnant Women	Female	16-21	24	17 (70.8%)	3 (12.5%)	4 (16.7%)
		Female	22-47	476	371 (77.9%)	32 (6.7%)	73 (15.3%)
	Total			500	388 (77.6%)	35 (7.0%)	77 (15.4%)
Mumps	Overall	Female	1-88	1544	1342 (86.9%)	43 (2.8%)	159 (10.3%)
		Male	1-88	968	818 (84.5%)	27 (2.8%)	123 (12.7%)
	Total			2512	2160 (86.0%)	70 (2.8%)	282 (11.2%)
	Pediatric	Female	1-21	134	107 (79.9%)	4 (3.0%)	23 (17.2%)
		Male	1-21	202	169 (83.7%)	7 (3.5%)	26 (12.9%)
	Total			336	276 (82.1%)	11 (3.5%)	49 (14.6%)
	Adult	Female	22-88	910	770 (84.6%)	33 (3.6%)	107 (11.8%)

		Male	22-88	766	649 (84.7%)	20 (2.6%)	97 (12.7%)
	Total			1676	1419 (84.7%)	53 (3.2%)	204 (12.2%)
	Pregnant Women	Female	16-21	24	22 (91.7%)	0 (0%)	2 (8.3%)
		Female	22-47	476	443 (93.1%)	6 (1.3%)	27 (5.7%)
	Total			500	465 (93.0%)	6 (1.2%)	29 (5.8%)
Rubella	Overall	Female	1-88	1544	1317 (85.3%)	49 (3.2%)	178 (11.5%)
		Male	1-88	968	788 (81.4%)	28 (2.9%)	152 (15.7%)
	Total			2512	2105 (83.8%)	77 (3.1%)	330 (13.1%)
	Pediatric	Female	1-21	134	107 (79.9%)	7 (5.2%)	20 (14.9%)
		Male	1-21	202	171 (84.7%)	6 (3.0%)	25 (12.4%)
	Total			336	278 (82.7%)	13 (3.9%)	45 (13.4%)
	Adult	Female	22-88	910	760 (83.5%)	27 (3.0%)	123 (13.5%)
		Male	22-88	766	617 (80.5%)	22 (2.9%)	127 (16.6%)
	Total			1676	1377 (82.2%)	49 (2.9%)	250 (14.9%)
	Pregnant Women	Female	16-21	24	21 (87.5%)	1 (4.2%)	2 (8.3%)
		Female	22-47	476	429 (90.1%)	14 (2.9%)	33 (6.9%)
	Total			500	450 (90.0%)	15 (3.0%)	35 (7.0%)
VZV	Overall	Female	1-88	1544	1334 (86.4%)	37 (2.4%)	173 (11.2%)
		Male	1-88	968	805 (83.2%)	26 (2.7%)	137 (14.2%)
	Total			2512	2139 (85.2%)	63 (2.5%)	310 (12.3%)
	Pediatric	Female	1-21	134	85 (63.4%)	7 (5.2%)	42 (31.3%)
		Male	1-21	202	131 (64.9%)	11 (5.4%)	60 (29.7%)
	Total			336	216 (64.3%)	18 (5.4%)	102 (30.4%)
	Adult	Female	22-88	910	794 (87.3%)	20 (2.2%)	96 (10.5%)
		Male	22-88	766	674 (88.0%)	15 (2.0%)	77 (10.1%)
	Total			1676	1468 (87.6%)	35 (2.1%)	173 (10.3%)
	Pregnant Women	Female	16-21	24	19 (79.2%)	1 (4.2%)	4 (16.7%)
		Female	22-47	476	436 (91.6%)	9 (1.9%)	31 (6.5%)
	Total			500	455 (91.0%)	10 (2.0%)	35 (7.0%)

B. Reproducibility study

A reproducibility of the DYNEX SmartPLEX MMRV IgG Assay Kit was conducted evaluating 22 serum samples at three sites located in the US using one kit and one

Multiplier Analyzer per site. Samples were tested in duplicate, two times a day, over 20 days for a total of 240 replicates per sample (one sample x two replicates x two runs per day x 20 days x 3 sites = 240 results per sample). The mean, standard deviation, and %CV were calculated for intra and inter-assay precision and inter-lot and inter-site precision for Measles, Mumps, Rubella and VZV, as shown in Tables 7A-7D below.

Table 7A: Measles Reproducibility Data

Category	Sample	N	Mean	Within Run		Between Run		Between Day		Between Site/ lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	5	240	0.21	0.014	6.4%	0.009	4.3%	0.004	1.7%	0.115	2.8%	0.018	8.4%
	6	240	0.38	0.029	7.8%	0.013	3.5%	0.007	1.9%	0.033	1.6%	0.034	8.9%
High Negative	8	240	0.67	0.043	6.4%	0.026	3.9%	0.011	1.7%	0.000	0.0%	0.051	7.7%
	10	240	0.69	0.045	6.6%	0.030	4.4%	0.015	2.2%	0.035	1.5%	0.058	8.3%
	3	240	0.73	0.064	8.8%	0.039	5.3%	0.000	0.0%	0.000	0.0%	0.075	10.3%
	2	240	0.82	0.038	4.6%	0.044	5.3%	0.000	0.0%	0.150	2.9%	0.063	7.6%
	19	240	0.85	0.054	6.3%	0.035	4.1%	0.000	0.0%	0.040	1.5%	0.066	7.7%
	21	240	0.88	0.061	7.0%	0.031	3.5%	0.000	0.0%	0.083	2.3%	0.072	8.2%
Equivocal	14	240	0.91	0.058	6.4%	0.041	4.5%	0.000	0.0%	0.062	2.0%	0.074	8.1%
	11	240	0.95	0.055	5.7%	0.040	4.2%	0.018	1.9%	0.166	3.3%	0.076	8.0%
	1	240	1.02	0.057	5.6%	0.056	5.5%	0.000	0.0%	0.153	3.3%	0.087	8.5%
	15	240	1.05	0.056	5.4%	0.047	4.4%	0.004	0.4%	0.056	1.7%	0.075	7.2%
Low Positive	17	240	1.23	0.095	7.7%	0.054	4.4%	0.017	1.4%	0.000	0.0%	0.111	9.0%
	18	240	1.25	0.066	5.3%	0.050	4.0%	0.033	2.6%	0.145	2.9%	0.097	7.7%
	16	240	1.27	0.085	6.7%	0.040	3.1%	0.006	0.5%	0.085	2.2%	0.098	7.7%
Moderate Positive	12	240	1.55	0.088	5.7%	0.051	3.3%	0.000	0.0%	0.072	1.8%	0.106	6.8%
	20	240	1.59	0.100	6.3%	0.038	2.4%	0.029	1.8%	0.102	2.4%	0.117	7.4%
	9	240	1.73	0.108	6.3%	0.057	3.3%	0.036	2.1%	0.361	5.6%	0.159	9.2%
	7	240	2.11	0.103	4.9%	0.080	3.8%	0.046	2.2%	0.050	1.5%	0.142	6.7%
	13	240	2.33	0.136	5.8%	0.071	3.1%	0.050	2.1%	0.078	2.0%	0.168	7.2%
High Positive	22	240	2.33	0.148	5.2%	0.082	2.9%	0.079	2.8%	0.158	2.8%	0.204	7.1%
	4	240	2.99	0.153	5.1%	0.092	3.1%	0.016	0.5%	0.210	3.1%	0.202	6.7%

Table 7B: Mumps Reproducibility Data

Category	Sample	N	Mean	Within Run		Between Run		Between Day		Between Site/ lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	19	240	0.37	0.023	6.2%	0.011	3.1%	0.013	3.5%	0.112	2.7%	0.030	8.2%
	2	240	0.47	0.024	5.2%	0.018	3.8%	0.011	2.4%	0.211	3.6%	0.036	7.7%
	3	240	0.53	0.028	5.3%	0.019	3.6%	0.013	2.5%	0.205	3.5%	0.040	7.7%
	8	240	0.57	0.038	6.6%	0.020	3.5%	0.000	0.0%	0.127	2.9%	0.046	8.0%
	1	240	0.60	0.035	5.8%	0.023	3.8%	0.022	3.6%	0.055	1.9%	0.048	8.1%

High Negative	6	240	0.64	0.034	5.4%	0.018	2.9%	0.008	1.2%	0.000	0.0%	0.040	6.2%
	18	240	0.68	0.035	5.1%	0.026	3.9%	0.025	3.7%	0.151	3.1%	0.054	8.0%
	12	240	0.71	0.037	5.2%	0.028	3.9%	0.019	2.7%	0.076	2.0%	0.052	7.3%
	13	240	0.75	0.045	5.9%	0.038	5.0%	0.000	0.0%	0.078	2.2%	0.061	8.1%
	7	240	0.78	0.044	5.7%	0.031	4.0%	0.024	3.0%	0.176	3.5%	0.065	8.3%
Equivocal	11	240	0.99	0.064	6.5%	0.021	2.2%	0.028	2.8%	0.273	4.5%	0.086	8.7%
	20	240	1.00	0.067	6.6%	0.047	4.7%	0.000	0.0%	0.057	2.0%	0.084	8.4%
	9	240	1.06	0.056	5.3%	0.039	3.7%	0.031	3.0%	0.046	1.6%	0.077	7.3%
Low Positive	16	240	1.36	0.073	5.4%	0.051	3.8%	0.011	0.8%	0.150	2.8%	0.097	7.2%
	22	240	1.39	0.065	4.7%	0.057	4.1%	0.033	2.3%	0.285	4.2%	0.109	7.8%
	15	240	1.47	0.084	5.7%	0.062	4.3%	0.055	3.7%	0.000	0.0%	0.118	8.0%
Moderate Positive	21	240	1.51	0.079	5.3%	0.054	3.6%	0.036	2.4%	0.039	1.4%	0.104	6.9%
	5	240	1.55	0.072	4.6%	0.075	4.8%	0.000	0.0%	0.156	2.9%	0.113	7.3%
	10	240	2.37	0.131	5.5%	0.114	4.8%	0.000	0.0%	0.039	1.5%	0.177	7.5%
	14	240	2.47	0.121	4.9%	0.084	3.4%	0.059	2.4%	0.265	3.8%	0.185	7.5%
High Positive	17	240	3.05	0.288	9.5%	0.145	4.8%	0.020	0.6%	0.046	2.3%	0.331	10.9%
	4	240	3.52	0.165	4.7%	0.146	4.2%	0.062	1.8%	0.119	2.4%	0.244	6.9%

Table 7C: Rubella Reproducibility Data

Category	Sample	N	Mean	Within Run		Between Run		Between Day		Between Site/ lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	6	240	0.41	0.017	4.0%	0.013	3.1%	0.003	0.8%	0.192	2.5%	0.023	5.7%
	5	240	0.50	0.021	4.2%	0.012	2.3%	0.003	0.6%	0.125	1.8%	0.026	5.2%
	19	240	0.59	0.026	4.4%	0.015	2.5%	0.009	1.5%	0.190	2.6%	0.035	5.9%
	12	240	0.60	0.024	4.1%	0.018	3.0%	0.009	1.4%	0.007	0.4%	0.031	5.2%
High Negative	9	240	0.60	0.026	4.3%	0.016	2.7%	0.011	1.8%	0.026	0.9%	0.033	5.5%
	13	240	0.60	0.043	7.0%	0.026	4.4%	0.000	0.0%	0.147	3.4%	0.054	9.0%
	8	240	0.61	0.027	4.5%	0.023	3.8%	0.000	0.0%	0.013	0.7%	0.036	5.9%
	3	240	0.75	0.029	3.8%	0.022	3.0%	0.000	0.0%	0.074	1.4%	0.038	5.1%
	2	240	0.85	0.037	4.3%	0.018	2.1%	0.010	1.2%	0.255	2.9%	0.049	5.8%
	21	240	0.88	0.032	3.7%	0.021	2.4%	0.015	1.7%	0.037	0.9%	0.043	4.8%
Equivocal	1	240	0.96	0.039	4.0%	0.031	3.2%	0.020	2.1%	0.170	2.5%	0.059	6.1%
	18	240	0.98	0.035	3.5%	0.031	3.2%	0.000	0.0%	0.068	1.3%	0.048	4.9%
	15	240	1.04	0.043	4.1%	0.025	2.4%	0.000	0.0%	0.040	1.0%	0.051	4.9%
	7	240	1.06	0.038	3.6%	0.036	3.4%	0.000	0.0%	0.133	1.9%	0.056	5.3%
Low Positive	11	240	1.17	0.043	3.7%	0.029	2.5%	0.021	1.8%	0.000	0.0%	0.055	4.8%
	20	240	1.31	0.058	4.4%	0.000	0.0%	0.017	1.3%	0.168	2.1%	0.066	5.1%
	16	240	1.33	0.045	3.4%	0.031	2.3%	0.000	0.0%	0.080	1.2%	0.057	4.3%
Moderate Positive	14	240	1.50	0.044	2.9%	0.031	2.1%	0.023	1.5%	0.011	0.4%	0.059	3.9%
	17	240	1.65	0.103	6.2%	0.000	0.0%	0.016	1.0%	0.068	1.7%	0.108	6.5%

	10	240	1.97	0.060	3.1%	0.061	3.1%	0.000	0.0%	0.000	0.0%	0.085	4.3%
	4	240	2.40	0.063	2.6%	0.063	2.6%	0.000	0.0%	0.011	0.4%	0.089	3.7%
High Positive	22	240	3.36	0.111	3.3%	0.069	2.0%	0.000	0.0%	0.000	0.0%	0.130	3.9%

Table 7D: VZV Reproducibility Data

Category	Sample	N	Mean	Within Run		Between Run		Between Day		Between Site/ lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	7	240	0.26	0.016	6.2%	0.007	2.8%	0.006	2.1%	0.065	1.9%	0.019	7.4%
	13	240	0.27	0.020	7.3%	0.011	4.1%	0.006	2.2%	0.000	0.0%	0.024	8.7%
High Negative	2	240	0.63	0.038	6.0%	0.017	2.7%	0.013	2.0%	0.020	1.0%	0.044	7.0%
	8	240	0.83	0.050	6.1%	0.023	2.8%	0.014	1.7%	0.013	0.8%	0.058	6.9%
	19	240	0.85	0.044	5.2%	0.036	4.3%	0.011	1.3%	0.000	0.0%	0.058	6.8%
Equivocal	12	240	1.02	0.043	4.2%	0.036	3.5%	0.018	1.8%	0.135	2.3%	0.063	6.2%
Low Positive	15	240	1.22	0.048	3.9%	0.047	3.8%	0.006	0.5%	0.000	0.0%	0.067	5.5%
	17	240	1.25	0.083	6.6%	0.035	2.8%	0.007	0.5%	0.084	2.2%	0.094	7.5%
	18	240	1.28	0.057	4.4%	0.043	3.4%	0.042	3.3%	0.000	0.0%	0.083	6.4%
	1	240	1.32	0.062	4.7%	0.063	4.8%	0.000	0.0%	0.000	0.0%	0.088	6.7%
	9	240	1.35	0.058	4.3%	0.051	3.7%	0.028	2.1%	0.000	0.0%	0.082	6.1%
Moderate Positive	20	240	1.63	0.083	5.1%	0.052	3.2%	0.000	0.0%	0.014	0.7%	0.099	6.1%
	6	240	1.69	0.069	4.1%	0.060	3.5%	0.011	0.7%	0.158	2.4%	0.100	5.9%
	5	240	1.98	0.091	4.6%	0.076	3.8%	0.000	0.0%	0.008	0.5%	0.119	6.0%
	3	240	2.48	0.105	4.2%	0.061	2.5%	0.051	2.0%	0.233	2.9%	0.150	6.1%
High Positive	22	240	2.65	0.100	3.8%	0.085	3.2%	0.000	0.0%	0.270	3.0%	0.153	5.8%
	21	240	2.66	0.117	4.4%	0.057	2.2%	0.040	1.5%	0.313	3.4%	0.164	6.2%
	14	240	2.7	0.103	3.8%	0.053	2.0%	0.073	2.7%	0.267	3.0%	0.159	5.9%
	11	240	3.01	0.115	3.8%	0.072	2.4%	0.081	2.7%	0.193	2.6%	0.176	5.9%
	10	240	3.03	0.114	3.8%	0.093	3.1%	0.037	1.2%	0.157	2.2%	0.166	5.5%
	16	240	3.06	0.126	4.1%	0.070	2.3%	0.039	1.3%	0.366	3.7%	0.188	6.2%
	4	240	3.34	0.128	3.8%	0.106	3.2%	0.090	2.7%	0.207	2.9%	0.212	6.4%

C. Within-Laboratory Precision study

A within-laboratory precision study was conducted evaluating 22 serum samples using three lots of the DYNEX SmartPLEX MMRV IgG Assay Kit and 1 DYNEX Multiplier Analyzer. Samples were tested in duplicate, two times a day for 20 days, for a total of 240 replicates per sample across all three-reagent kit lots (one sample x two replicates x two runs x 20 days x three reagent kit lots = 240 results per sample) to measure reagent lot-to-lot precision, as shown in Tables 8A-8D below.

Table 8A: Measles Within-Laboratory Precision Data

Category	Sample	N	Mean	Within Run		Between Run		Between Day		Between Lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	5	240	0.22	0.013	5.9%	0.008	3.8%	0.005	2.4%	0.193	3.6%	0.018	8.3%
	6	240	0.38	0.026	6.8%	0.018	4.8%	0.009	2.5%	0.001	0.3%	0.033	8.7%
High Negative	8	240	0.68	0.044	6.5%	0.029	4.3%	0.013	2.0%	0.000	0.0%	0.054	8.0%
	10	240	0.70	0.044	6.3%	0.028	3.9%	0.016	2.3%	0.000	0.0%	0.055	7.8%
	3	240	0.74	0.053	7.2%	0.024	3.3%	0.019	2.6%	0.000	0.0%	0.061	8.3%
	2	240	0.82	0.048	5.8%	0.035	4.3%	0.020	2.4%	0.188	3.7%	0.069	8.4%
	19	240	0.87	0.049	5.6%	0.037	4.3%	0.000	0.0%	0.077	2.0%	0.064	7.4%
	21	240	0.89	0.062	7.0%	0.041	4.6%	0.014	1.5%	0.003	0.4%	0.076	8.5%
Equivocal	14	240	0.92	0.060	6.6%	0.039	4.2%	0.010	1.1%	0.071	2.2%	0.075	8.2%
	11	240	0.96	0.055	5.7%	0.035	3.7%	0.027	2.8%	0.067	2.0%	0.073	7.5%
	1	240	1.01	0.055	5.5%	0.045	4.4%	0.021	2.1%	0.139	3.0%	0.080	7.9%
	15	240	1.06	0.067	6.3%	0.055	5.2%	0.000	0.0%	0.004	0.5%	0.086	8.2%
Low Positive	17	240	1.26	0.071	5.6%	0.056	4.5%	0.037	3.0%	0.000	0.0%	0.098	7.7%
	16	240	1.28	0.077	6.0%	0.060	4.7%	0.000	0.0%	0.116	2.7%	0.103	8.0%
	18	240	1.29	0.076	5.9%	0.045	3.5%	0.030	2.3%	0.076	2.1%	0.097	7.5%
Moderate Positive	12	240	1.57	0.095	6.1%	0.046	3.0%	0.039	2.5%	0.021	1.1%	0.114	7.3%
	20	240	1.61	0.086	5.4%	0.071	4.4%	0.046	2.8%	0.089	2.3%	0.126	7.8%
	9	240	1.75	0.098	5.6%	0.065	3.7%	0.036	2.1%	0.216	3.7%	0.139	7.9%
	7	240	2.14	0.118	5.5%	0.079	3.7%	0.000	0.0%	0.044	1.4%	0.145	6.8%
	13	240	2.36	0.139	5.9%	0.104	4.4%	0.000	0.0%	0.022	1.1%	0.175	7.4%
High Positive	22	240	2.90	0.136	4.7%	0.100	3.5%	0.078	2.7%	0.073	1.8%	0.193	6.7%
	4	240	3.04	0.134	4.4%	0.140	4.6%	0.032	1.0%	0.137	2.6%	0.211	6.9%

Table 8B: Mumps Within-Laboratory Precision Data

Category	Specimen	N	Mean	Within Run		Between Run		Between Day		Between Lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	19	240	0.37	0.022	5.9%	0.016	4.3%	0.000	0.0%	0.437	6.4%	0.036	9.7%
	2	240	0.47	0.027	5.7%	0.012	2.5%	0.007	1.5%	0.497	6.3%	0.042	9.0%
	3	240	0.53	0.031	5.9%	0.019	3.6%	0.003	0.6%	0.360	5.2%	0.046	8.7%
	8	240	0.56	0.029	5.1%	0.019	3.3%	0.000	0.0%	0.322	4.2%	0.042	7.4%
High Negative	1	240	0.60	0.034	5.6%	0.020	3.3%	0.005	0.8%	0.379	5.1%	0.050	8.3%
	6	240	0.63	0.031	4.9%	0.022	3.5%	0.015	2.3%	0.130	2.5%	0.044	6.9%
	18	240	0.68	0.037	5.4%	0.021	3.0%	0.014	2.1%	0.434	5.7%	0.059	8.7%
	12	240	0.71	0.037	5.2%	0.020	2.8%	0.019	2.6%	0.045	1.4%	0.047	6.7%
	13	240	0.74	0.040	5.4%	0.028	3.8%	0.000	0.0%	0.231	3.6%	0.055	7.5%
	7	240	0.78	0.043	5.5%	0.023	2.9%	0.011	1.4%	0.359	4.8%	0.062	8.0%
Equivocal	11	240	0.99	0.049	4.9%	0.033	3.3%	0.018	1.8%	0.471	5.8%	0.084	8.5%
	20	240	1.01	0.081	8.0%	0.000	0.0%	0.053	5.2%	0.261	5.7%	0.113	11.1%
	9	240	1.06	0.052	4.9%	0.039	3.7%	0.029	2.8%	0.245	3.8%	0.082	7.8%
Low Positive	16	240	1.36	0.073	5.4%	0.043	3.2%	0.000	0.0%	0.321	4.3%	0.102	7.5%
	22	240	1.39	0.063	4.5%	0.046	3.3%	0.030	2.1%	0.454	5.5%	0.113	8.1%
	15	240	1.43	0.079	5.5%	0.054	3.8%	0.005	0.4%	0.052	1.6%	0.099	6.9%
Moderate Positive	21	240	1.52	0.079	5.2%	0.046	3.0%	0.040	2.7%	0.157	2.8%	0.108	7.2%
	5	240	1.54	0.071	4.6%	0.044	2.8%	0.024	1.6%	0.325	3.9%	0.105	6.8%
	10	240	2.35	0.111	4.7%	0.056	2.4%	0.042	1.8%	0.160	2.4%	0.143	6.1%
	14	240	2.49	0.121	4.9%	0.048	1.9%	0.061	2.5%	0.479	5.5%	0.199	8.0%
High Positive	17	240	2.99	0.152	5.1%	0.081	2.7%	0.026	0.9%	0.212	3.0%	0.196	6.6%
	4	240	3.48	0.163	4.7%	0.102	2.9%	0.000	0.0%	0.186	2.6%	0.213	6.1%

Table 8C: Rubella Within-Laboratory Precision Data

Category	Sample	N	Mean	Within Run		Between Run		Between Day		Between Lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	6	240	0.42	0.019	4.4%	0.010	2.5%	0.008	2.0%	0.111	1.9%	0.024	5.8%
	5	240	0.50	0.020	4.0%	0.005	1.1%	0.011	2.3%	0.099	1.6%	0.025	5.0%
	19	240	0.60	0.024	4.0%	0.013	2.1%	0.015	2.5%	0.094	1.7%	0.033	5.5%
High Negative	8	240	0.61	0.028	4.5%	0.012	1.9%	0.012	1.9%	0.172	2.4%	0.035	5.8%
	12	240	0.61	0.025	4.0%	0.013	2.2%	0.005	0.9%	0.133	1.8%	0.030	5.0%
	9	240	0.62	0.025	4.1%	0.021	3.4%	0.005	0.9%	0.116	1.9%	0.035	5.7%
	13	240	0.62	0.031	5.0%	0.021	3.4%	0.000	0.0%	0.018	0.8%	0.037	6.0%
	3	240	0.75	0.029	3.9%	0.013	1.7%	0.014	1.9%	0.137	1.8%	0.037	5.0%
	2	240	0.86	0.032	3.7%	0.023	2.6%	0.019	2.2%	0.026	0.8%	0.044	5.1%
	21	240	0.90	0.036	4.0%	0.022	2.5%	0.018	2.0%	0.058	1.3%	0.047	5.2%
Equivocal	1	240	0.96	0.039	4.1%	0.020	2.1%	0.021	2.2%	0.008	0.4%	0.049	5.1%
	18	240	1.00	0.038	3.8%	0.015	1.5%	0.014	1.4%	0.029	0.7%	0.043	4.4%
	15	240	1.05	0.039	3.8%	0.022	2.1%	0.009	0.9%	0.135	1.7%	0.049	4.7%
	7	240	1.08	0.036	3.3%	0.016	1.5%	0.028	2.6%	0.047	1.0%	0.049	4.6%
Low Positive	11	240	1.18	0.042	3.6%	0.029	2.4%	0.017	1.4%	0.058	1.1%	0.055	4.7%
	20	240	1.34	0.063	4.7%	0.014	1.0%	0.032	2.4%	0.037	1.1%	0.074	5.5%
	16	240	1.34	0.048	3.6%	0.026	1.9%	0.025	1.9%	0.008	0.4%	0.061	4.5%
Moderate Positive	14	240	1.52	0.048	3.2%	0.035	2.3%	0.029	1.9%	0.036	0.8%	0.067	4.4%
	17	240	1.68	0.049	2.9%	0.034	2.0%	0.028	1.6%	0.000	0.0%	0.066	3.9%
	10	240	2.01	0.063	3.1%	0.040	2.0%	0.027	1.3%	0.000	0.0%	0.079	3.9%
	4	240	2.44	0.063	2.6%	0.064	2.6%	0.028	1.1%	0.000	0.0%	0.094	3.9%
High Positive	22	240	3.37	0.101	3.0%	0.065	1.9%	0.069	2.1%	0.100	1.4%	0.146	4.3%

Table 8D: VZV Within-Laboratory Precision Data

Category	Sample	N	Mean	Within Run		Between Run		Between Day		Between Lot		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Negative	7	240	0.26	0.015	5.9%	0.005	2.0%	0.009	3.3%	0.086	2.2%	0.019	7.4%
	13	240	0.26	0.018	6.9%	0.004	1.6%	0.006	2.2%	0.079	2.2%	0.020	7.8%
High Negative	2	240	0.63	0.033	5.2%	0.018	2.8%	0.011	1.8%	0.079	1.8%	0.040	6.4%
	8	240	0.83	0.042	5.0%	0.024	2.9%	0.014	1.7%	0.199	3.0%	0.056	6.7%
	19	240	0.84	0.040	4.8%	0.021	2.5%	0.024	2.9%	0.154	2.6%	0.056	6.7%
Equivocal	12	240	1.00	0.045	4.5%	0.027	2.7%	0.022	2.2%	0.104	1.9%	0.060	6.0%
Low Positive	15	240	1.22	0.050	4.1%	0.037	3.0%	0.014	1.1%	0.093	1.7%	0.067	5.5%
	17	240	1.24	0.059	4.7%	0.026	2.1%	0.003	0.2%	0.156	2.2%	0.070	5.6%
	18	240	1.29	0.057	4.4%	0.024	1.9%	0.020	1.6%	0.118	1.8%	0.069	5.4%
	1	240	1.31	0.064	4.9%	0.032	2.4%	0.028	2.2%	0.055	1.4%	0.079	6.1%
	9	240	1.35	0.059	4.4%	0.042	3.1%	0.000	0.0%	0.124	2.0%	0.078	5.7%
	20	240	1.63	0.079	4.9%	0.044	2.7%	0.027	1.6%	0.139	2.3%	0.102	6.2%

Moderate Positive	6	240	1.69	0.074	4.4%	0.049	2.9%	0.000	0.0%	0.118	1.9%	0.094	5.6%
	5	240	2.00	0.082	4.1%	0.055	2.8%	0.043	2.2%	0.269	3.3%	0.126	6.3%
	3	240	2.45	0.095	3.9%	0.059	2.4%	0.046	1.9%	0.082	1.5%	0.126	5.2%
High Positive	21	240	2.62	0.104	4.0%	0.076	2.9%	0.071	2.7%	0.050	1.3%	0.151	5.8%
	22	240	2.63	0.097	3.7%	0.070	2.7%	0.055	2.1%	0.209	2.6%	0.148	5.6%
	14	240	2.69	0.100	3.7%	0.070	2.6%	0.062	2.3%	0.133	2.0%	0.147	5.5%
	11	240	3.01	0.107	3.6%	0.106	3.5%	0.000	0.0%	0.115	1.8%	0.161	5.3%
	16	240	3.03	0.113	3.7%	0.084	2.8%	0.013	0.4%	0.156	2.0%	0.154	5.1%
	10	240	3.06	0.111	3.6%	0.075	2.5%	0.060	2.0%	0.160	2.1%	0.160	5.2%
	4	240	3.31	0.120	3.6%	0.108	3.3%	0.059	1.8%	0.147	2.2%	0.186	5.6%

D. Method Comparison Testing

Performance of the DYNEX SmartPLEX MMRV IgG Assay Kit was evaluated against corresponding commercially available Measles, Mumps, Rubella and VZV immunoassays using a total of 2512 retrospective serum samples. Serum specimens from adults (N=1676), pregnant woman (N=500) and pediatric (N=336) were evaluated.

The method comparison testing was performed at two US laboratory testing sites using a total of 2512 retrospective human serum specimens obtained from commercial vendors (Table 9).

Table 9: Category of Specimens Tested in the Study

Category	Specimen number	Total (%)
Overall Human Serum Specimens Obtained from all Commercial Vendors	2512	100.0%
Overall Human Serum Specimens Obtained from Commercial Vendors from Pediatrics Normal	336	13.4%
Overall Human Serum Specimens Obtained from Commercial Vendors from MMRV Adults	1676	66.7%
Overall Human Serum Specimens Obtained from Commercial Vendors from Pregnant Women	500	19.9%

To demonstrate the clinical performance of the DYNEX SmartPLEX MMRV IgG Assay Kit, Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA)

between the results of the DYNEX SmartPLEX MMRV IgG Assay Kit and an FDA-cleared comparator tests were calculated.

At the end of the study, specimens with reported Equivocal results on the test device (DYNEX SmartPLEX MMRV IgG Assay Kit) and comparator device were identified and retested in accordance with their Instructions for Use (IFUs). If the Equivocal Specimens remain Equivocal on the comparator device, they were retested with two additional FDA cleared methods. Specimen results from all 3 comparator devices were interpreted by a "2/3 rule" in which a comparator algorithm was used to obtain a consensus. The results from the comparator algorithm were then compared to the SmartPLEX MMRV IgG Assay results using a 3 by 3 analysis approach in which any remaining equivocal results were counted against the clinical performance of the SmartPLEX MMRV IgG Assay. The 3 by 3 analysis approach was used to calculate the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the SmartPLEX MMRV IgG Assay Kit and the "Final Comparator Result".

Table 10: Demographic information per Cohort

Measure	Adult Females (N=910)	Adult Males (N=766)	All Adults (N=1676)	Pediatric Females (N=134)	Pediatric Males (N=202)	All Pediatrics (N=336)	Pregnant Women (N=500)	All Subjects (N=2512)
Age (years)	≥ 22	≥ 22	≥ 22	≥1 and ≤ 21	≥1 and ≤ 21	≥1 and ≤ 21	≥ 16	1-88
N	910	766	1676	134	202	336	500	2512
Mean	36.4	42.2	39.1	15	13.6	14.1	32.3	34.4
Standard Deviation (SD)	11.0	14.9	13.3	5.4	5.7	5.6	6.2	14.1
Median	34.0	39.0	35.0	16.5	15.0	14.1	32.0	32.0
Min	22.0	22.0	22.0	1.0	0.0	1.0	16.0	1.0
Max	84.0	88.0	88.0	21.0	21.0	21	47.0	88.0

Performance results are shown in the tables below.

Table 11A: Clinical Performance per Cohort – Measles IgG

Cohort	Measles IgG		Final comparator results				Percentage Agreement	
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pediatrics	SmartPLEX MMRV	Positive	250	0	0	250	87.70%	100%
		Equivocal	12	0	0	12	250/285	51/51

		Negative	18	5	51	74	(83.4 – 91.0%)	(93.0 - 100%)
		Total	280	5	51	336		
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pregnant women	SmartPLEX MMRV	Positive	387	0	0	387	84.30%	100%
		Equivocal	34	0	0	34	387/459	41/41
		Negative	31	7	41	79	(80.7 – 87.4%)	(91.4 - 100%)
		Total	452	7	41	500		
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pediatric and Adult	SmartPLEX MMRV	Positive	1545	0	1	1546	87.00%	98.70%
		Equivocal	70	0	2	72	1545/1775	234/237
		Negative	137	23	234	394	(85.4 – 88.5%)	(96.3 – 99.6%)
		Total	1752	23	237	2012		

Table 11B: Clinical Performance per Cohort – Mumps IgG

Cohort	Mumps IgG		Final comparator results				Percentage Agreement	
			Positive	Equivocal	Negative	Total	PPA*(95% CI)*	NPA *(95% CI)*
Pediatrics	SmartPLEX MMRV	Positive	270	0	6	276	94.40%	76.00%
		Equivocal	5	0	6	11	270/286	38/50
		Negative	8	3	38	49	(91.1 - 96.5%)	(62.6 - 85.7%)
		Total	283	3	50	336		
			Positive	Equivocal	Negative	Total	PPA*(95% CI)*	NPA *(95% CI)*
Pregnant women	SmartPLEX MMRV	Positive	463	0	2	465	96.90%	90.90%
		Equivocal	5	0	0	5	463/478	20/22
		Negative	5	5	20	30	(94.9 – 98.1%)	(72.2 – 97.5%)
		Total	473	5	22	500		
			Positive	Equivocal	Negative	Total	PPA*(95% CI)*	NPA *(95% CI)*
Pediatric and Adult	SmartPLEX MMRV	Positive	1672	2	22	1696	94.70%	78.90%
		Equivocal	32	1	28	61	1672/1765	194/246
		Negative	47	14	194	255	(93.6 – 95.7%)	(73.3 – 83.5%)
		Total	1751	17	244	2012		

Table 11C: Clinical Performance per Cohort – Rubella IgG

Cohort	Rubella IgG		Final comparator results				Percentage Agreement	
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pediatrics	SmartPLEX MMRV	Positive	278	0	0	278	92.70%	100%
		Equivocal	14	0	0	14	278/300	36/36
		Negative	8	0	36	44	(89.1 – 95.1%)	(90.4 - 100%)
		Total	300	0	36	336		
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pregnant women	SmartPLEX MMRV	Positive	449	0	0	449	92.00%	100%
		Equivocal	15	0	0	15	449/488	12/12
		Negative	24	0	12	36	(89.3 – 94.1%)	(75.8 - 100%)
		Total	488	0	12	500		
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pediatric and Adult	SmartPLEX MMRV	Positive	1656	0	1	1657	92.40%	99.50%
		Equivocal	61	0	0	61	1656/1793	218/219
		Negative	71	5	218	294	(91.0 – 93.5%)	(97.5 – 99.9%)
		Total	1788	5	219	2012		

Table 11D: Clinical Performance per Cohort – VZV IgG

Cohort	VZV IgG		Final comparator results				Percentage Agreement	
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pediatrics	SmartPLEX MMRV	Positive	215	0	2	217	91.50%	93.90%
		Equivocal	11	3	4	18	215/235	92/98
		Negative	4	5	92	101	(87.2 – 94.4%)	(87.3 – 97.2%)
		Total	230	8	98	336		
			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pregnant women	SmartPLEX MMRV	Positive	453	2	1	456	97.20%	84.80%
		Equivocal	6	1	2	9	453/466	28/33
		Negative	5	2	28	35	(95.3 – 98.4%)	(69.1 – 93.3%)
		Total	464	5	31	500		

			Positive	Equivocal	Negative	Total	PPA *(95% CI)*	NPA *(95% CI)*
Pediatric and Adult	SmartPLEX MMRV	Positive	1667	8	11	1686	96.70%	88.00%
		Equivocal	27	13	14	54	1667/1723	243/276
		Negative	17	12	243	272	(95.8 – 97.5%)	(83.7 – 91.4%)
		Total	1711	33	268	2012		

E. Potential Cross-Reactivity

Potential cross-reactivity for the DYNEX SmartPLEX MMRV IgG Assay Kit was determined by testing serum samples from individuals containing antibodies to other microorganisms or with medical conditions unrelated to MMRV infections. This study was performed to determine whether IgG antibodies in serum specimens from patients with known infectious diseases interfere with the reported results of the DYNEX SmartPLEX MMRV IgG Assay Kit generating false positive results. Serum specimens that were IgG antibody positive for the infectious disease agents shown in Table 12 were used for the study. These specimens were obtained from vendors and confirmed negative with the predicate MMRV assays prior to testing with the DYNEX SmartPLEX MMRV IgG Assay Kit. All potential cross-reactants samples were tested in duplicate, with the DYNEX SmartPLEX MMRV IgG Assay. The results were compared to the results obtained from the predicate test (summarized in the table below). All specimens evaluated were negative with both assays, except one specimen for HSV 2. The HSV 2 sample had an Equivocal result for Mumps with the DYNEX SmartPLEX MMRV IgG Assay Kit while had a high negative result with the Trinity predicate assay.

The DYNEX SmartPLEX MMRV IgG Assay Kit cross reactivity study was not evaluated sufficiently for Hepatitis C Virus (HCV), Hepatitis B Surface Antigen (HBsAg), Herpes Simplex Virus 1 (HSV1), Herpes Simplex Virus 2 (HSV2), Toxoplasma gondii due to the lack of samples availability of samples that are positive for the disease states but negative for each of the measurands.

Table 12: Potential Cross-Reactivity

Specimen Type	Measles IgG		Mumps IgG		Rubella IgG		VZV IgG	
	N	Negative Agreement	N	Negative Agreement	N	Negative Agreement	N	Negative Agreement
Antinuclear antibodies (ANA)	5	5/5	5	5/5	5	5/5	5	5/5
Anti-Cytomegalovirus (CMV)	6	6/6	5	5/5	5	5/5	8	8/8
Anti-Epstein-Barr Viral Capsid Antigen (EBV)	10	10/10	11	11/11	8	8/8	6	6/6

Anti-HBs, [Hepatitis B Surface Antigen (HbsAg)]	5	5/5	0	-	1	1/1	0	-
Anti-Hepatitis C (HCV)	7	7/7	2**	2/2	4**	4/4	1**	1/1
Anti-Herpes Simplex Virus 1 (HSV 1)	3**	3/3	1**	1/1	3**	3/3	3**	3/3
Anti-Herpes Simplex 2 (HSV 2)	1**	1/1	3**	2/3*	2**	2/2	3**	3/3
Anti-Parvovirus B19	2**	2/2	1**	1/1	0	-	1**	1/1
Anti-Toxoplasma gondii	2**	2/2	0	-	1**	1/1	2**	2/2
Anti-Myeloma M-protein	7	7/7	10	10/10	7	7/7	6	6/6
Anti-Mumps, anti-Rubella, and anti-VZV‡	7	7/7	-	N/A	-	N/A	-	N/A
Anti-Measles, anti-Rubella, and anti-VZV‡	-	N/A	6	6/6	-	N/A	-	N/A
Anti-Measles, anti-Mumps, and anti-VZV‡	-	N/A	-	N/A	18	18/18	-	N/A
Anti-Measles, anti-Rubella, and anti-Rubella‡	-	N/A	-	N/A	N/A	-	14	14/14

Note: * One HSV 2 sample had an Equivocal result for Mumps with the DYNEX SmartPLEX MMRV IgG Assay Kit while had a high negative result with the Trinity predicate assay.
** Potential cross-reactivity was not well assessed due to limited sample size.
‡ Three measurands were evaluated together for potential cross reactivity.

F. Interfering Substances

The DYNEX SmartPLEX MMRV IgG Assay Kit was evaluated for potential interference of endogenous substances using negative, low positive, and high positive serum samples for Measles, Mumps, Rubella, and VZV antibodies spiked with potential interfering substances. A non-spiked sample was used as a control for each measurand. No interference was observed at the maximum concentrations listed in Table 13.

Table 13: Potential Interfering Substances Evaluated

Interfering Substance	Concentration
Albumin	50 g/dL
Bilirubin (conjugated)	5 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Cholesterol total	250 mg/dL
Hemoglobin	500 mg/dL
Triglyceride total	500 mg/dL

G. Shelf Life

The shelf-life stability of the DYNEX SmartPLEX MMRV IgG Assay Kit was evaluated for storage at 2-8°C for up to 25 months. Unopened test kits were stored and tested at one month intervals using human specimens. The results demonstrated that unopened SmartPLEX MMRV IgG Assay Kit is stable at 2-8°C for up to 19 months. The self-life storage of the unopened DYNEX SmartPLEX MMRV IgG Assay Kit is assigned as 18 months at the recommended storage temperature of 2-8°C.

10. CONCLUSION:

The performance data as documented above demonstrates that the DYNEX SmartPLEX MMRV IgG Assay Kit performs comparably to the predicate device that is currently marketed for the same intended use.