

**SPECIAL 510(k): Device Modification  
ODE Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K120439

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

Trade Name:

BioPlex™ 2200 EBV IgG Panel

BioPlex™ 2200 Syphilis IgG Panel

510(k) number: K063866 and K062211

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED**. There is a labeling change to change the frequency of QC testing from once per pack and per day to once per day or per new reagent pack lot. This labeling change does not affect the intended use
3. The modification presented in this 510(k) is a change in the frequency of the QC testing recommendations specified in the labeling. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
4. Comparison Information (similarities and differences)

Similarities for the BioPlex 2200 Syphilis IgG Panel

Feature	Predicate device	Modified Device
Intended Use/ Indications for Use	The BioPlex® 2200 Syphilis IgG kit is a multiplex flow immunoassay intended for the qualitative detection Treponema pallidum in human serum. The test system, when used in conjunction with non-treponemal based assays, provides serological evidence of infection with T. pallidum. This test system also confirms reactive test results from non-treponemal based screening assays.  The Syphilis IgG kit is intended for use with the Bio-Rad BioPlex 2200 System.	Same
Device Components	Reagent Pack, Negative control, Multi- Analyte Positive controls and Multiple Calibrators	Same
Technical Specifications	Analytical and Clinical Performance Characteristics	Same
Fundamental Scientific Technology	Multiplex flow immunoassay	Same

Differences for the BioPlex 2200 Syphilis IgG Panel

Feature	Predicate device	Modified Device
Frequency of Reagent Pack QC Testing	QC once per pack and per day	QC once per day or per new reagent pack lot

Similarities for the BioPlex 2200 EBV IgG Panel

Feature	Predicate device	Modified Device
Intended Use/ Indications for Use	<p>The BioPlex<sup>®</sup> 2200 EBV IgG kit is a multiplex flow immunoassay intended for the qualitative detection of IgG antibodies to three (3) separate EBV antigens; Epstein-Barr Virus Nuclear Antigen-1 (EBV NA-1), Viral Capsid Antigen (EBV VCA), and Early Antigen diffuse (EBV EA-D) in human serum. The test system can be used in conjunction with the BioPlex 2200 EBV IgM kit as an aid in the laboratory diagnosis of infectious mononucleosis (IM).</p> <p>The EBV IgG kit is intended for use with the Bio-Rad BioPlex 2200 System.</p> <p>Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants. Assay performance characteristics have not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, and other EBV-associated lymphomas.</p>	Same
Device Components	Reagent Pack, Negative control, Multi- Analyte Positive controls and Multiple Calibrators	Same
Technical Specifications	Analytical and Clinical Performance Characteristics	Same
Fundamental Scientific Technology	Multiplex flow immunoassay	Same

Differences for the BioPlex 2200 EBV IgG Panel

Feature	Predicate device	Modified Device
Frequency of Reagent Pack QC Testing	QC once per pack and per day	QC once per day or per new reagent pack lot

## 5. Design Control Activities Summary

### a) Risk Analysis:

A Failure Modes and Effects Analysis was used to facilitate, capture and quantify potential impacts of the Low Signal Pack (LSP) phenomenon. The sponsor considered guidance from 21 CFR 860 and IVDD (98/79/EC) when evaluating the severity of the effects for each of the assays. Additionally potential misuse of the products was considered during the risk analysis.

### b) Verification and Validation activities:

Contamination studies were performed to assess the effect of proteases from bacterial and mold contaminants on remediated Syphilis and EBV IgG reagent packs. The results showed that the current (remediated) formulations provide adequate protection against bacteria and mold contamination. Even at extreme contamination levels, remediated Syphilis and EBV IgG kits exhibit only minimal signal loss. The percent recovery ratios of the QC controls were within the acceptable limits and the negative controls were within the specified range as per the product specifications.

The results indicated that the individual assays within the remediated Syphilis and EBV IgG panels were not significantly affected by the microbial contaminants.

The Residual Risk acceptability criteria (RPN score) was established at low level of concern according to the submitter's Risk Management Plan, and hence does not require any additional mitigation activity.

### c) Declaration of Conformity

A "Declaration of Conformity" statement was submitted duly signed by the responsible individuals. The statements indicate that;

- i) As required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
- ii) The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Based on the conclusion of the risk management report, the modified QC procedure fulfills the requirements of the specifications of the design control process. Therefore, the performance of the modified QC test frequency is substantially equivalent to the current cleared kit.

## 6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.

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(Reviewer's Signature)

(Date)

Comments

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