

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

To: THE FILE

RE: DOCUMENT NUMBER K090847,
 Bio-Rad Platelia™ Toxo IgM

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 (delete/add items as necessary):

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

Platelia Toxo IgM TMB kit, K013837

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

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.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for a product name change, catalogue number, sample volume, sample dilution, reagent composition, preservative change, quality control criteria, procedure and stability.

The fundamental scientific technology of the modified device has not changed. 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.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and test performance.

Table: Summary of Design Modifications and Required Validation Activities

Design Change Category	Description of Change	Design Validation
Composition / Concentration	<u>Preservative change</u> : replaced thimerosal with Proclin™300 in the following reagents: <ul style="list-style-type: none"> - Wash Solution - Negative Control - Cutoff Control - Pos Control - Conjugate - Diluent 	<ul style="list-style-type: none"> - Precision Study - Interference Study - Determination of the Cut-Off Value - Cross Reactivity Study - Clinical Evaluation - Wash Solution 10x vs 20x Study - Robustness Study - Stability Studies
	<u>Ready-To-Use reagent</u> : the Chromogen / TMB Substrate solution has been prepared as a ready to use reagent and no longer requires preparation by the user prior to use.	

	<p><u>Concentration change:</u> the re-constitution instructions have been changed for the following reagents.</p> <ul style="list-style-type: none"> - Wash Solution (formerly 10x; now 20x) - Conjugate (formerly 50x; now 101x) 	
Design Change Category	Description of Change	Design Validation
Procedure	<p><u>Sample dilution change:</u> the sample dilution has been changed from 1/101 to 1/21. The procedure formerly required 10 µl of sample and now requires 15 µl of sample.</p> <p><u>Washing procedure changes:</u> two washing procedures have changed as follows:</p> <ul style="list-style-type: none"> - Pre-washing of the microplate prior to the addition of samples is no longer required. - Four washing cycles are now required before addition of the Conjugate, where three cycles were required previously. <p><u>Quality control criteria change:</u> the quality control criteria have been changed as follows:</p> <ul style="list-style-type: none"> - The negative control criteria has changed from ≤ 0.100 OD to ≤ 0.150 OD - The positive control criteria have been replaced with a mean calibrator OD criteria requiring the mean calibrator OD to be ≥ 0.300 OD. - The ratio and corresponding acceptance criteria for the mean cut-off control OD vs. the negative control OD have been inverted. <p>The following quality control criteria remain unchanged:</p> <ul style="list-style-type: none"> - The requirement that the individual OD of each replicate of the calibrator must not differ more than 20% of the cutoff value. - The ratio of the positive control OD to the mean calibrator OD must be ≥ 1.80. 	<ul style="list-style-type: none"> - Precision Study - Interference Study - Determination of the Cut-Off Value - Cross Reactivity Study - Clinical Evaluation - Wash Solution 10x vs 20x Study - Robustness Study - Stability Studies

Design Change Category	Description of Change	Design Validation
Procedure (cont...)	<p><u>Stability information changes:</u> the reagent stability claims have changed as follows:</p> <ul style="list-style-type: none"> - The stability claim for the microplate strips has been increased from one month to 8 weeks when stored at 2 – 8°C. - The stability claims for the negative control, calibrator, positive control, conjugate, diluent, and chromogen solution have clarified to be stable for up to 8 weeks once opened and stored at 2 – 8°C. - The stability claim for the wash solution has been clarified to be stable for up to 2 weeks once diluted and stored at 2 – 30°C. Once opened the concentrated washing solution is stable until the expiration date indicated on the label when stored at 2 – 30°C. - The stability claim for diluted <i>T. gondii</i> antigen was removed as the reconstituted antigen solution is for immediate use. - The stability claim for diluted conjugate has been clarified to be stable after reconstitution for 8 hours at 18 – 30°C and 4 weeks at 2 – 8°C. 	<ul style="list-style-type: none"> - Precision Study - Interference Study - Determination of the Cut-Off Value - Cross Reactivity Study - Clinical Evaluation - Wash Solution 10x vs 20x Study - Robustness Study - Stability Studies

5. A **Design Control Activities Summary** which includes:

- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

- c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, 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) A statement signed by the individual responsible, that 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.

The sponsor submitted all the Design Control studies and they are acceptable. The submitter has provided the design control information as specified in The New 510(k) Paradigm.

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