



6. Do not heat inactivate before use.
7. Specimen containing precipitate or particulate matter should be clarified by centrifugation prior to use.
8. Specimen should be free from particulate matter and microbial contamination.

#### PRECAUTIONS

1. Bring all reagents and specimen to room temperature before use.
2. Do not pipette any material by mouth.
3. Do not eat, drink or smoke in the area where testing is done.
4. Use protective clothing and wear gloves when handling samples.
5. Use absorbent sheet to cover the working area.
6. Immediately clean up any spills with sodium hypochlorite.
7. All specimens and standards should be considered potentially infectious and discarded appropriately.
8. Neutralize acid containing waste before adding hypochlorite.
9. Do not use kit after the expiry date.
10. Do not mix components of one kit with another.
11. Always use new tip for each specimen and reagent.
12. Do not allow liquid from one well to mix with other wells.
13. Do not let the strips dry in between the steps.

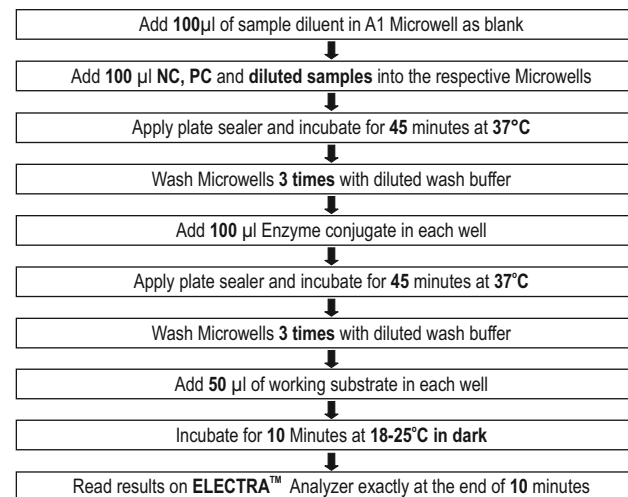
#### REAGENT PREPARATION

- All reagents should be brought to room temperature (18-25°C) and mixed by gently inverting or swirling prior to use. Do not induce foaming.
- Dilute wash buffer 20 times (for example add 5ml concentrated buffer to 95 ml distilled or deionized water). Mix well before use.
- Prepare a Working Substrate by Mixing Substrate A and Substrate B in equal volume (1:1 ratio) before addition to the micro-wells.

No. of Strips	1	2	3	4	5	6	7	8	9	10	11	12
Substrate- A µl	250	450	650	850	1050	1250	1450	1650	1850	2050	2250	2450
Substrate- B µl	250	450	650	850	1050	1250	1450	1650	1850	2050	2250	2450

#### TEST PROCEDURE

1. Place the desired number of coated strips into the holder.
2. Prepare 1:40 dilutions by adding 5µl of the test samples to 200 µl of sample diluent. **(Please do not dilute Positive Control and Negative Control, they are ready for use).** Mix well.
3. For the reagent blank, dispense 100µl of sample diluent in A1 well position, followed by negative control and positive control. (recommended in duplicates). Dispense 100µl of diluted sera into the appropriate wells. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 45 minutes at 37°C.
4. Wash each well three times by filling approximately 350µl diluted wash buffer & blot dry.
5. Dispense 100µl of enzyme conjugate to each well and incubate for 45 minutes 37°C.
6. Wash each well three times by filling approximately 350µl diluted wash buffer & blot dry.
7. Add 50 µl of working Substrate (A+B) in all the micro-wells. Keep away from direct light while adding the substrate.
8. Cover the **ELECTRA™** microplate and incubate for 10 minutes at room temperature (18-25°C) in dark.
9. Read the **ELECTRA™** micro-plate exactly at 10 minutes in **ELECTRA™ Analyzer**. If **ELECTRA™** micro-plate is not read between 10-15 minutes the test results should be considered as invalid.



#### RUN CRITERIA

The test run may be considered valid provided the following criteria are met:

1. The Toxo IgM Index for Negative and Positive Control should be in the range stated on the labels.

#### CALCULATION OF RESULTS

1. Calculate the average value of the RLU of the negative control.
2. Calculate the cutoff value using the following formula:  
Cut-Off (RLU) = 10 x Mean RLU of Negative Control.
3. Calculate the Toxo IgM Index using the following formula:  
Toxo IgM Index= Sample RLU/ Cut-Off (RLU).

#### INTERPRETATION OF THE RESULT

IgM Index Value	Result
IgM Index value <0.90	Negative
IgM Index value 0.91-1.1	Grey zone
IgM Index value >1.1	Positive

#### PERFORMANCE CHARACTERISTICS

##### Specificity and Sensitivity:

A total of 96 patient samples were used to evaluate specificity and sensitivity of the test. Toxoplasma IgM test results were compared to a commercial kit results:

		Reference CLIA			
		N	E	P	Total
<b>ELECTRA™ TOXO IgM CLIA</b>	N	83 (D)	0	0 (B)	83
	E	0	0	0	0
	P	5 (C)	0	8 (A)	13
	Total	88	0	8	96

Sensitivity = 100%

Specificity = 94%