CONSORTIUM of NRLs for KIT QUALITY

Under NACP III

E-mail: nari@nariindia.org
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☎ 020 - 27331200
Fax No. 0091-20-27121071

To
The Project Director,
West Bengal State AIDS Prevention & Control Society
Swasthya Bhavan,
Sec-V, Salt Lake, Kol-91

Date: 20-02-2015

Subject: Evaluation of HBsAg (ELISA) Test Kits.

Dear Sir,

I am sending you the evaluation report of the HBsAg ELISA Kit, Lot No. TBMB 1425 (Kit ID: K-15-04) manufactured by Transasia Bio-Medicals Ltd., sent by you for evaluation, which we have received on 28-01-2015.

The details of evaluation mentioned in separate pages attached herewith.

Kind regards.

20/02/2015

Dr. M. K. Saha
In-Charge, NRL on Q
National Institute of Cholera and Enteric Diseases.

National Institute of Cholera & Enteric Diseases, CONSORTIUM of NRLs for KIT Quality, ICMR, Govt. of India

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KIT EVALUATION REPORT

A) General Information

1. Consortium kit ID : K-15-04
2. Date of receipt of kit : 28/01/15
3. Name of the kit : ERBA LISA HEPATITIS B
4. Manufacturer : Transasia Bio-Medicals Ltd.
5. Batch number/lot No. : TBMB 1425
6. Date of manufacture : 01/2015
7. Date of expiry : 12/2015
8. Assay Principle : Sandwich ELISA
9. No. of invalid assays* : 00

   (ELISA Test)

   *Comments : Nil

B) Details of the panel

1. Panel type : HBV Panel
2. Panel ID : ConQ09/01
3. Panel size : 382
4. Panel composition : 92 confirmed positive samples, and 290 confirmed negative samples

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I.C.M.R.

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C) Results:

1. Sensitivity and Specificity of the kit:

Test kit	Standard Test		
	Positive	**Negative**	**Total**
Positive.	92	00	92
Negative	00	290	290
Total	92	290	382

• Sensitivity: 92/ (92+00) x100 = 100%

• Specificity: 290 / (290+00) x100 = 100%

(Note: - Range at 95% Confidence Interval as per NACO guidelines)

2. Kit Appraisal

	Rating	Poor	Satisfactory	Good
Kit instructions	clarity		√	
	presentation		√	
	content		√	
	Safety instructions		√	
Reagent and packing			√	
Labeling			√	
Ease of performance			√	
Interpretation clarity			√	

Comments: Nil

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D) Additional information

1. **Interfering sample results:** All these samples were negative for HIV/HCV/HBsAg. These were used to provide additional information. This data is not used for calculating specificity and sensitivity.

Category	Number tested	Number discordant
Parasitic	00	NA
TB	00	NA
AI	00	NA
MP	00	NA

2. **Sero conversion panel results**: Not Assessed

Panel 1

- Panel Name:
- Manufacture:
- Lot No & Date of manufacture:
- Panel size:

Panel number	Day of bleed	Reference result obtained in Western Blot provided by the manufacturer of seroconversion panel	Result obtained by kit under evaluation

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Panel 2

- Panel Name:
- Manufacture:
- Lot No & Date of manufacture:
- Panel size:

Panel number	Day of bleed	Reference result obtained in Western Blot provided by the manufacturer of seroconversion panel	Result obtained by kit under evaluation

Panel 3

- Panel Name:
- Manufacture:
- Lot No & Date of manufacture:
- Panel size:

Panel number	Day of bleed	Reference result obtained in Western Blot provided by the manufacturer of seroconversion panel	Result obtained by kit under evaluation

Summary of report: The acceptable level of Sensitivity is ≥ 99.8% and specificity is ≥ 98.0%. For this kit the sensitivity is **100%** and specificity is **100%.**

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20/02/2015

Signature and date
In charge- NRL on Q

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1. Analytical Report No. : K-15-04
2. Name of the Product : ERBA LISA HEPATITIS B
3. Batch/Lot No. : TBMB 1425
4. Name of the manufacturer : Transasia Bio-Medicals Ltd.
5. Manufacturing Date : 01/2015
6. Expiry date : 12/2015

TECHNICAL. SPECIFICATIONS	Remarks of Laboratory (NRL):
1. Assay should have sensitivity of .≥ level at 99.8% or more and should have the Specificity of ≥ 98.0% or more.	YES/~~NO~~*. The sensitivity of the Assay is 100%. YES/~~NO~~*. The specificity of the Assay is 100%.
2. Should be third generation ELISA Kit with solid phase micro plate ELISA	YES/~~NO~~*. Remarks if any: Nil
3. The kit should be based on 'sandwich principle' of ELISA for the detection of Hepatitis B Surface Antigen (HBsAg) in human serum or plasma. .	YES/~~NO~~*. Remarks if any: Nil
4. ELISA plate should be coated with Anti-HBs Antibody (mouse monoclonal)	YES/~~NO~~*. Remarks if any: ELISA Plate is coated with goat polyclonal anti-HBsAg.
5. The assay should have reactive and non reactive control with each kit.	YES/~~NO~~*. Remarks if any: Nil
6. Adequate literature detailing the component, methodology, validity criteria, performance characteristics, storage conditions and expiry date should be provided with each kit.	YES/~~NO~~*. Remarks if any: Nil
7. The package size should be 96 wells per kit.	YES/~~NO~~*. Remarks if any: Nil

*Strike out whatever is not applicable.

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Signature of the Lab. Authority

Name: Dr. M. K. Saha

Date: 20/02/2015

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