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INDIAN COUNCIL OF  
MEDICAL RESEARCH REGIONAL MEDICAL RESEARCH  
CENTRE, PORT BLAIR

आई सी एम आर – क्षेत्रीय आयुर्विज्ञान  
अनुसंधान केन्द्र, पोर्ट ब्लेयर  
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार  
कल्याण मंत्रालय, भारत सरकार

ICMR - Regional Medical Research Centre,  
Port Blair

Department of Health Research, Ministry of Health  
and Family Welfare, Government of India

Dated: 02<sup>nd</sup> June 2020

Dear Sir

Point of care test for diagnosis of leptospirosis (Truenat) has been evaluated for its indices accuracy at Regional Medical Research Centre, WHO Collaborating Centre for Diagnosis, Research, Reference and Training in Leptospirosis, Port Blair. The test showed excellent agreement with real-time PCR on clinical samples. Further the test was able to detect the entire DNA from clinical isolates recovered from different endemic states of India.

Since the test showed sensitivity and specificity in excess of 95% in clinical specimens obtained from three different endemic regions of the country, it can be concluded that the test would be a useful tool for rapid diagnosis of leptospirosis with minimum facilities and the test results can be obtained in an one hour duration that facilities to provide specific therapy, heist patient care even at peripheral health care centres where minimum facilities available. The evaluation report is attached herewith.

Sincerely

*Sunish*  
02/06/2020  
Dr. I.P.Sunish

Scientist-E& Director office coordinator

ICMR-Regional Medical Research Centre, Port Blair

To  
Director  
Molbio Diagnostics Pvt. Ltd.  
Plot no. L-46, Phase II D, Verna Industrial Estate,  
Verna, Goa – 403722



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INDIAN COUNCIL OF MEDICAL RESEARCH REGIONAL MEDICAL RESEARCH CENTRE, PORT BLAIR

WHO COLLABORATING CENTRE FOR DIAGNOSIS, RESEARCH, REFERENCE AND TRAINING ON LEPTOSPIROSIS

आई सी एम आर – क्षेत्रीय आयुर्विज्ञान  
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Dr . P. Vijayachari  
Director.

Ref .Dir /1-1/Trunat / 2020/ 09

Date: 26<sup>th</sup> June 2020

To  
Dr Chandrasekhar Nair,  
Director,  
Molbio Diagnostics Pvt Ltd., Goa

Sub: Evaluation report - Truenat™

Dear Dr. Nair,

Please find herewith enclosed the evaluation report on comparison of three lots of Truenat™  
LTS-Lot nos. ELP01, ELP02 and ELP03 for detection of Leptospirosis . The lots were  
manufactured by M/S Molbio Diagnostics Pvt. Ltd., at their manufacturing site Plot no. L-46,  
Phase II D, Verna Industrial estate, Verna, Goa – 403722.

With regards

P. Vijayachari

## The evaluation report

The comparison of three lots of assays, Truenat™ LTS – Lot No. viz ELP01, ELP02 and ELP03 for the detection of Leptospirosis manufactured by M/S Molbio Diagnostics Pvt. Ltd., at their manufacturing site Plot no. L-46, Phase II D, Verna Industrial estate, Verna, Goa – 403722.

<b>Name of the Tests</b>	Truenat™ LTS, Chip-based Real Time PCR test for <i>Leptospira</i>
<b>Manufacturer</b>	Molbio Diagnostics Pvt Ltd, Plot no. L-46, Phase II D, Verna Industrial estate, Verna, Goa – 403722
<b>Configuration of test Panel</b>	A panel of 30 samples comprising 10 known positives and 20 known negative plasma samples. Samples were run in parallel, using ICMR approved Realtime PCR
<b>Principle of the Test</b>	Isolation of nucleic acid based on an automated cartridge based protocol and nucleic acid amplification by real time polymerase chain reaction [PCR].
<b>Protocol</b>	<p>Truenat™ LTS tests were run on Truelab Real Time Micro PCR systems. This system comprises of the Truelab™ UnoDx, a fully automated and battery operated Real Time PCR analyser, which runs the specific Truenat™ chip based Real Time PCR test and Trueprep™ Auto, an automated, battery operated sample preparation device.</p> <p>Performance comparison was done using ICMR approved Real-time PCR as per the standard and published protocol for confirmatory diagnosis of leptospirosis at , ICMR RMRC , Portblair.</p>
<b>Result Summary</b>	<p><b>Inter lot analysis of Truenat™ LTS assay</b></p> <p>30 plasma samples were extracted using Trueprep Auto system. The elute were run in parallel on three test lots of Truenat™ LTS chips (Lot numbers: ELP01, ELP02 and ELP03 .All positives (n=10) were detected as positive on three lots of Truenat™ LTS chips. All negatives (n=20), were also shown "Not Detected" result on three lots of Truenat™ LTS chips. Concordance observed was 100% when compared with ICMR approved Realtime PCR for all three lots on the tested panel of samples.</p>
<b>Conclusion</b>	All three lots of Truenat™ LTS: ELP01, ELP02, ELP03 supplied for evaluation by the manufacturer showed good performance and 100% concurrence with confirmatory test (RT -PCR) used on the panel used for the study. No significant lot to lot variation was observed as seen from the raw data.

For Director.

M. Rm<sup>o</sup>

• 26/6/2020

(M. RAJAMANI)

RESEARCH ASSISTANT  
ICMR - RMRC, Port Blair

**ANNEXURE - I**

**Experimental data:**

A panel of 30 plasma samples were analysed. Samples were run in parallel using ICMR approved RT - PCR and Truelab workstation. Three lots of test chips (for Truenat™ LTS ) were used for evaluation.

Lot number: ELP01

Date of testing-20/06/2020

Sample	Positive control(RMRC) CT Value	Negative Control CT Value	Sample CT Value	Truenat Results	RMRC Results
1	31	Not detected	24	Positive	Positive
2	32	Not detected	29	Positive	Positive
3	27	Not detected	20	Positive	Positive
4	29	Not detected	18	Positive	Positive
5	28	Not detected	24	Positive	Positive
6	29	Not detected	29	Positive	Positive
7	32	Not detected	29	Positive	Positive
8	33	Not detected	27	Positive	Positive
9	29	Not detected	24	Positive	Positive
10	30	Not detected	24	Positive	Positive
11	30	Not detected	ND	Negative	Negative
12	31	Not detected	ND	Negative	Negative
13	30	Not detected	ND	Negative	Negative
14	29	Not detected	ND	Negative	Negative
15	29	Not detected	ND	Negative	Negative
16	32	Not detected	ND	Negative	Negative
17	31	Not detected	ND	Negative	Negative
18	30	Not detected	ND	Negative	Negative
19	32	Not detected	ND	Negative	Negative
20	31	Not detected	ND	Negative	Negative
21	33	Not detected	ND	Negative	Negative
22	31	Not detected	ND	Negative	Negative
23	29	Not detected	ND	Negative	Negative
24	27	Not detected	ND	Negative	Negative
25	28	Not detected	ND	Negative	Negative
26	30	Not detected	ND	Negative	Negative
27	31	Not detected	ND	Negative	Negative
28	29	Not detected	ND	Negative	Negative
29	33	Not detected	ND	Negative	Negative
30	31	Not detected	ND	Negative	Negative

*For Director*

*M. Rm<sup>o</sup>*

*26/6/2020*

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Lot number: ELP02

Sample	Positive control(RMRC) CT Value	Negative Control CT Value	Truenat CT Value	Truenat Results	RMRC Results
1	30	Not detected	24	Positive	Positive
2	29	Not detected	28	Positive	Positive
3	32	Not detected	23	Positive	Positive
4	29	Not detected	18	Positive	Positive
5	29	Not detected	24	Positive	Positive
6	30	Not detected	30	Positive	Positive
7	29	Not detected	29	Positive	Positive
8	32	Not detected	27	Positive	Positive
9	31	Not detected	24	Positive	Positive
10	30	Not detected	24	Positive	Positive
11	31	Not detected	ND	Negative	Negative
12	32	Not detected	ND	Negative	Negative
13	30	Not detected	ND	Negative	Negative
14	29	Not detected	ND	Negative	Negative
15	30	Not detected	ND	Negative	Negative
16	29	Not detected	ND	Negative	Negative
17	29	Not detected	ND	Negative	Negative
18	31	Not detected	ND	Negative	Negative
19	31	Not detected	ND	Negative	Negative
20	29	Not detected	ND	Negative	Negative
21	31	Not detected	ND	Negative	Negative
22	29	Not detected	ND	Negative	Negative
23	31	Not detected	ND	Negative	Negative
24	27	Not detected	ND	Negative	Negative
25	32	Not detected	ND	Negative	Negative
26	28	Not detected	ND	Negative	Negative
27	30	Not detected	ND	Negative	Negative
28	29	Not detected	ND	Negative	Negative
29	31	Not detected	ND	Negative	Negative
30	30	Not detected	ND	Negative	Negative

For Director.

M.R.<sup>o</sup>

26/6/2020

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Lot number – ELP03

Sample	Positive control(RMRC) CT Value	Negative Control CT Value	Sample CT Value	Truenat Results	RMRC Results
1	31	Not detected	24	Positive	Positive
2	29	Not detected	28	Positive	Positive
3	31	Not detected	23	Positive	Positive
4	28	Not detected	18	Positive	Positive
5	29	Not detected	24	Positive	Positive
6	31	Not detected	29	Positive	Positive
7	30	Not detected	29	Positive	Positive
8	31	Not detected	27	Positive	Positive
9	32	Not detected	24	Positive	Positive
10	30	Not detected	25	Positive	Positive
11	32	Not detected	ND	Negative	Negative
12	31	Not detected	ND	Negative	Negative
13	29	Not detected	ND	Negative	Negative
14	33	Not detected	ND	Negative	Negative
15	33	Not detected	ND	Negative	Negative
16	29	Not detected	ND	Negative	Negative
17	32	Not detected	ND	Negative	Negative
18	32	Not detected	ND	Negative	Negative
19	32	Not detected	ND	Negative	Negative
20	32	Not detected	ND	Negative	Negative
21	30	Not detected	ND	Negative	Negative
22	31	Not detected	ND	Negative	Negative
23	30	Not detected	ND	Negative	Negative
24	27	Not detected	ND	Negative	Negative
25	30	Not detected	ND	Negative	Negative
26	30	Not detected	ND	Negative	Negative
27	28	Not detected	ND	Negative	Negative
28	28	Not detected	ND	Negative	Negative
29	30	Not detected	ND	Negative	Negative
30	29	Not detected	ND	Negative	Negative

For Director.

M. Rn<sup>o</sup>

26/6/2020

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