CE

Truenat®

Scrub T

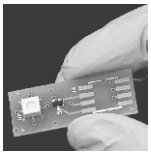
Chip-based Real Time PCR Test for ScrubTyphus

1. INTENDED USE

REF **Truenat® Scrub T (REF 601450005 / 601450020 / 601450025 / 601450050 / 601450100 / 601450200)** is an automated point-of-care or near patient chip-based Real Time-Polymerase Chain Reaction (PCR) test for the quantitative detection of Scrub typhus bacteria in whole blood/Serum/Plasma specimens. **Truenat® Scrub T** runs on the **Truelab®** Real Time Quantitative micro PCR Analyzers. **Truenat® Scrub T** is a single use *in vitro* diagnostics test meant for professional use in near-patient, laboratory or any healthcare settings, by healthcare professionals or any user appropriately trained by a representative of Molbio Diagnostics.

2. INTRODUCTION

Scrub typhus is an acute febrile illness caused by *Orientia tsutsugamushi* following the bite of infected larval mite. Approximately one million cases are known to occur annually in Asia Pacific region. Diagnosis is often difficult since most of the clinical manifestations, such as fever, headache, nausea, myalgia, abdominal pain, lymphadenopathy and maculopapular rash are nonspecific. Complications of scrub typhus such as jaundice, renal failure, pneumonitis, ARDS, septic shock,myocarditis, and meningoencephalitis usually develop after the first week of illness. Most cases of scrub typhus occur in Asia Pacific countries, however, recent reports document establishment in the Arabian Peninsula, Chile, and possibly Kenya. Currently available DNA molecular tests lack sensitivity to reproducibly detect the low level of scrub typhus bacteria circulating in blood. Scrub typhus diagnosis mainly relies on serologic tests, particularly the indirect immunofluorescence assay (IFA), whereby the illness is identified by a 4-fold increase in antibody titers in paired sera and/or a positive IgM titer in a single serum sample. The laboratory tests often have limited diagnostic accuracy and are generally in limited supply in resource-limited or outpatient settings. In those settings, point-of-care testing (POCT) can be useful in making a quick diagnosis. The **Truenat®** Real Time Quantitative micro PCR System enables decentralization and near patient diagnosis and bacterial load monitoring of Scrub typhus by making real time PCR technology rapid, simple, robust and user friendly, thereby offering "sample to result" capability even at resource limited settings. This is achieved through a combination of lightweight, portable, mains/battery operated **Truelab®** Real Time micro Quantitative PCR Analyzer and **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Device and room temperature stable **Truenat®** micro PCR chips and **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep kits so that even the peripheral laboratories with minimal infrastructure and minimally trained technician can easily perform these tests routinely in their facilities and report PCR results in less than an hour. Moreover, with these devices PCR testing can also be initiated in the field level, on site. **Truenat® Scrub T** is a disposable, room temperature stable, micro PCR chip with dried down PCR reagents for performing Real Time PCR test for Scrub typhus bacteria and runs on the **Truelab®** Real Time Quantitative micro PCR Analyzer. All the components of **Truenat®** pouch are nuclease-free. It requires only six (6) µL of purified DNA to be added to the reaction well for the analysis. The intelligent chip also carries test and batch related information. The **Truenat® Scrub T** chip also stores information of used chips to prevent any accidental re-use of the chip.



NOTE :Truelab®/ Truenat® / Trueprep® / Truepet® are all trademarks of Molbio Diagnostics Private Limited.

The Truelab® Real Time micro PCR Analyzer is protected by the following patents and patents granted: IN 2313/CHE/2007 (Patent No. 281573), WO2009/047804 and corresponding claims of any foreign counterpart(s) thereof.

The Truenat® micro PCR chip is protected by the following patents and patents pending: IN 2312/CHE/2007, WO 2009/047805 and corresponding claims of any foreign counterpart(s) thereof.

3. PRINCIPLE OF THE TEST

Truenat® Scrub T works on the principle of Real Time Polymerase Chain Reaction (PCR) based on Taqman chemistry. The patient sample (whole blood / plasma / serum) is first pre-treated using the **Trueprep® AUTO** Universal Sample Pre-treatment Pack. The DNA from the patient sample is first extracted using **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep kit. The cartridge from the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit contains pre-loaded Internal Positive Control (IPC), it is a synthetic plasmid construct provided in a stable formulation preloaded into Cartridges which is co-extracted along with sample nucleic acids, thereby validating the process from extraction to PCR run. The DNA extract is analyzed using the **Truenat® Scrub T** Chip-based Real Time Polymerase Chain Reaction (PCR) test and the **Truelab®** Real Time Quantitative micro PCR Analyzer. The **Truenat® Scrub T** chip is placed on the chip tray of the The **Truelab®** Real Time Quantitative micro PCR Analyzer. Six (6) µL of the purified DNA is then dispensed using the provided calibrated micropipette and tip into the microtube containing freeze dried PCR reagents and allowed to stand for 30-60 seconds to get a clear solution. ⚠ No mixing by tapping, shaking or by reverse pipetting should be done. Six (6) µL of this clear solution is then pipetted out using the same pipette and tip and dispensed into the reaction well of the **Truenat® Scrub T** chip and the test is started. A positive amplification causes the dual labeled fluorescent probes in the **Truenat® Scrub T** chip to release the fluorophore in an exponential manner which is then captured by the built-in opto-electronic sensor and displayed as amplification curve on the analyzer screen, on a real time basis during the test run. The Cycle threshold (Ct) is defined as the number of amplification cycles required for the fluorescent signal to cross the threshold (i.e. exceed the background signal). Ct levels are inversely proportional to the amount of target nucleic acid in the sample. (i.e the lower the Ct level the greater is the amount of target nucleic acid in the sample). In the case of negative samples, amplification does not occur and a horizontal amplification curve is displayed on the screen during the test run. At the end of the test run, a SCRUB TYPHUS DETECTED or NOT DETECTED result is displayed and in positive cases, Ct values and copies per milliliter (copies/ml) is also displayed on the screen. Based on the detection of the Internal Positive Control (IPC), the validity of the test run is also displayed. The IPC is a full process control that undergoes all the processes the specimen undergoes from extraction to amplification thereby validating the test run from sample to result. Absence of or shift of IPC Ct beyond a pre-set range in case of negative samples invalidates the test run. While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid. The results can be printed using the **Truelab®** micro PCR printer or transferred to the lab computer/or any remote computer via Wifi network or 4G/3G/GPRS network. Upto 20000 test results can be stored on the analyzer for future recall and reference.

4. TARGET SELECTION

The target sequence for this assay is the *(htrA) gene* of *Orientia tsutsugamushi.*

5. CONTENTS OF THE Truenat® Scrub T KIT

A. Individually sealed pouches

B. Package insert

Each individually sealed pouch contains:

1. **Truenat® Scrub T** micro PCR chip (1 No.)
2. Microtube with freeze dried PCR reagents (1 No.)
3. DNase and RNase free pipette tip (1 No.)
4. Desiccant pouch (1 No.)

Pack sizes of **Truenat® Scrub T KIT**

REF	601450005	601450020	601450025	601450050	601450100	601450200
Σ	5T	20T	25T	50T	100T	200T

6. CONTENTS OF THE Trueprep® AUTO Universal Sample Pre-treatment Pack

A. Lysis buffer.

B. Disposable transfer pipette(graduated).

C. Package Insert.

REF	60205AB05	60205AB20	60205AB25	60205AB50	60205AB100
Σ	5T	20T	25T	50T	100T

7. STORAGE, HANDLING AND STABILITY

1. **Truenat® Scrub T** test is stable for two (2) years from the date of manufacture if stored between 2-30°C. It is also stable for one (1) month at temperatures up to 45°C. Avoid exposure to light or elevated temperatures (above recommended levels). Do not freeze.
2. **Trueprep® AUTO** Universal Sample Pre-treatment Pack is stable for two (2) years from the date of manufacture if stored between 2-40°C. It is also stable for one (1) month at temperatures upto 45°C. Do not freeze.
3. **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit is stable for two (2) years from the date of manufacture if stored between 2°C to 40°C. It is also stable for one (1) month at temperatures up to 45°C. Avoid exposure to sunlight.
4. Do not open the pouch until ready to test. Make sure to start the test promptly after 30-60 seconds of adding the elute to the microtube.
5. Do not use the pouch if torn.
6. Do not use pouches that have passed the expiration date.

8. MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

REF **Truelab®** Real Time micro PCR Workstation (REF 623010001 / 633010001 / 643010001 / 653010001) consisting of

1. **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Device (REF603041001/603042001).
2. **Truelab® Uno Dx/Truelab® Duo/Truelab® Quattro** Real Time Quantitative micro PCR Analyzer (REF603021001/603022001/603023001).
3. **Truelab®** micro PCR Printer (REF 603050001).
4. **Truepet®** SPA fixed volume precision micropipette - 6 µl (REF 604070006).
5. **Truelab®** Microtube Stand (REF 603070001).

Also required additionally are: **Trueprep® AUTO** Universal Sample Pre-treatment Pack (REF60205AB05 / REF60205AB20 / REF60205AB25 / REF60205AB50 / REF60205A100 / REF60205A200), **Trueprep® AUTO** Universal Cartridge Based Sample Prep Kit (REF60203AR05 / REF60203AR25 / REF60203AR50 / REF60203AR100 / REF60203AR200) or **Trueprep® AUTO v2** Universal Cartridge Based Sample Prep Kit (REF60207AR05 / REF60207AR25 / REF60207AR50 / REF60207AR100 / REF60207AR200), **Truenat®** Positive Control Kit - Panel V (REF801050008) Powder free disposable gloves, waste disposal container with lid.

9. SPECIMEN PREPARATION FOR EXTRACTION WITH Trueprep® AUTO/AUTO v2

Truenat® Scrub T requires purified nucleic acids from whole blood/plasma collected in EDTA anticoagulant or serum specimen that are extracted using the **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge based Sample Prep kit. Sample must be pre-treated using **Trueprep® AUTO** Universal Sample Pre-treatment pack. Transfer 250 µl of whole blood or 500 µl of plasma/serum specimen using the transfer pipette provided into the Lysis buffer tube provided and mix well. Use the entire content of lysis buffer tube containing the specimen for further procedure with the **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Device and **Trueprep® AUTO/AUTO v2** Universal Cartridge Based Sample Prep Kit (Refer to the User Manual of Trueprep® **AUTO/AUTO v2** Universal Cartridge Based Sample Prep device and the package insert of Sample Prep kit for details).

10. SAFETY PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Bring all reagents and specimen to room temperature (2-30°C) before use.
3. Do not use kit beyond expiry date.
4. Carefully read the user manuals, package inserts and Material Safety Data Sheets (MSDS) of all the components of the **Truenat®** point-of-care real time PCR system before use.
5. Good laboratory practices are recommended to avoid contamination of specimens or reagents.
6. All materials of human origin should be handled as though potentially infectious.
7. Do not pipette any material by mouth.
8. Do not eat, drink, smoke, apply cosmetics or handle contact lenses in the area where testing is done.
9. Use protective clothing and wear disposable gloves when handling samples and while performing sample extraction.
10. Do not substitute assay components / reagents with any other components / reagents.
11. Each single-use **Truenat®** chip is used to process one test. Do not reuse chip.

11. PROCEDURAL PRECAUTIONS

1. Check all packages before using the kit. Damage to the packaging does not prevent the contents of the kit from being used. However, if the outer packaging is damaged the user must confirm that individual components of the kit are intact before using them.
2. Do not perform the test in the presence of reactive vapours (e.g. from sodium hypochlorite, acids, alkalis or aldehydes) or dust.
3. While retrieving the **Truenat® Scrub T** chip, microtube and the DNase and RNase free pipette tip from the pouch, ensure that neither bare hands nor gloves that have been used for previous tests run are used.
4. Ensure that the colour of the desiccant pouch is orange after opening a sealed **Truenat®** chip pouch. If the colour of the desiccant pouch changes from orange to white due to the absorption of moisture, do not use the contents of the **Truenat®** chip pouch.

12. PROCEDURAL LIMITATIONS

1. Optimal performance of this test requires appropriate specimen collection, handling, storage and transport to the test site.
2. Though very rare, mutations within the highly conserved regions of the target genome where the **Truenat®** assay primers and/or probe bind may result in the under-quantitation of or a failure to detect the presence of the concerned pathogen.
3. The instruments and assay procedures are designed to minimize the risk of contamination by PCR amplification products. However, it is essential to follow good laboratory practices and ensure careful adherence to the procedures specified in this package insert for avoiding nucleic acid contamination from previous amplifications, positive controls or specimens.
4. A specimen for which the **Truenat®** assay reports “Not Detected” cannot be concluded to be negative for the concerned pathogen. As with any diagnostic test, results from the **Truenat®** assay should be interpreted in the context of other clinical and laboratory findings.

13. CLEANING AND DECONTAMINATION

1. Spills of potentially infectious material should be cleaned up immediately with absorbent paper tissue and the contaminated area should be decontaminated with disinfectants such as 0.5% freshly prepared sodium hypochlorite [10 times dilution of 5% sodium hypochlorite (household bleach)] before continuing work.
2. Sodium hypochlorite should not be used on an acid-containing spill unless the spill-area is wiped dry first. Materials used to clean spills, including gloves, should be disposed off as potentially bio-hazardous waste e.g. in a biohazard waste container.

14. TEST PROCEDURE

(Please also refer the **Truelab®** Real Time micro PCR Analyzer user manual)

1. Switch on the **Truelab®** Analyzer
2. Select user and enter password.
3. For **Truelab® Uno Dx**, select the test profile for "Scrub typhus" to be run from the Profiles Screen on the Analyzer screen. For **Truelab® Duo/Quattro**, select the Bay (Idle1/2) for Duo and (Idle1/2/3/4) for Quattro from the Status Screen to view the Profiles Screen. Select the test profile for "Scrub typhus" to be run from the Profiles Screen on the Analyzer screen.
4. Enter the patient details as prompted in the **Truelab®** Real Time micro PCR Analyzer screen.
5. Press Start Reaction.
6. For **Truelab® Uno Dx**, Press the eject button to open the chip tray. For **Truelab® Duo/Quattro**, the chip tray opens automatically on tapping the "Start Reaction" button.
7. Open a pouch of **Truenat® Scrub T** and retrieve the micro PCR chip and the microtube.
8. Place the **Truenat® Scrub T** micro PCR chip on the chip tray without touching the white reaction well. The reaction well should be facing up and away from the Analyzer. Gently press the chip to ensure that it has seated in the chip tray properly.
9. Place the microtube containing freeze dried PCR reagents in the microtube stand provided along with the **Truelab®** Real Time micro PCR workstation after ensuring that white pellet of dried PCR reagents remains at the bottom of the microtube. Remove the microtube cap and dispose it off as per the section on "Disposal and Destruction" (Section 17). Using the filter barrier tip provided in the pouch, pipette out six (6) µL of the purified DNA from the Elute Collected Tube into the microtube. Allow it to stand for 30-60 seconds to get a clear solution. ⚠ Do not mix it by tapping, shaking or by reverse pipetting. Using the same filter barrier tip, pipette out six (6) µL of this clear solution and dispense into the centre of the white reaction well of the **Truenat® Scrub T** chip. Take care not to scratch the internal well surface and not to spill elute on the outside of the well. Dispose off the microtip as per the section on "Disposal and Destruction" (Section 17).
10. For **Truelab® Uno Dx**, slide the chip tray containing the **Truenat® Scrub T** chip-based Real Time PCR test loaded with the sample into the **Truelab®** Analyzer. Press Done on the "Please Load Sample" Alert message. For **Truelab® Duo/Quattro**, select "YES" at the Please load Sample prompt. Chip tray will close automatically and the reaction will start.
11. Read the result from the screen.
12. After the reaction is completed, for **Truelab® Uno Dx**, push the Eject button to eject the chip tray. For **Truelab® Duo/Quattro**, tap the "Open/Close Tray" button to eject the chip tray.
13. Take out the **Truenat® Scrub T** Chip-based Real Time PCR test at end of the test and dispose it off as per the section on "Disposal and Destruction".
14. Turn on **Truelab®** micro PCR printer and select print on the screen for printing out hard copy of the results. Test results are automatically stored and can be retrieved any time later. (Refer to the **Truelab®** Analyzer manual).
15. Switch off the **Truelab®** Analyzer.

15. RESULTS AND INTERPRETATIONS

Two amplification curves are displayed on the **Truelab®** Real Time micro PCR Analyzer screen to indicate the progress of the test. Both the target and the internal positive control (IPC) curves will take a steep, exponential path when the fluorescence crosses the threshold value in case of positive samples. The time taken (Ct) of the specimen will depend on the number of target DNA in the sample. The curve will remain horizontal throughout the test duration and the IPC curve will take an exponential path in case of negative samples. In case the IPC curve remains horizontal in a negative sample, the test is considered as Invalid. At the end of the test run, the results screen will display "DETECTED" for Positive result or "NOT DETECTED" for Negative results The result screen would also display the bacterial load in copies/ml for positive specimen. The result screen also displays the validity of the test run as "VALID" or "INVALID". Invalid samples have to be repeated with fresh specimen from the sample preparation stage. *While IPC will co-amplify in most positive cases also, in some specimen having a high target load, the IPC may not amplify, however the test run is still considered valid.

16. QUALITY CONTROL PROCEDURES

To ensure that the **Truelab®** Real Time Quantitative micro PCR Analyzer is working accurately, run positive and negative controls from time to time. The Positive Control Kit Panel - V (REF801050008) containing Positive Control and Negative Control must be ordered separately. It is advisable to run controls under the following circumstances. ● Whenever a new shipment of test kits is received. ● When opening a new test kit lot. ● If the temperature of the storage

area falls outside of 2-30°C. ● By each new user prior to performing testing on clinical specimen.

17. DISPOSAL AND DESTRUCTION

1. Submerge the used content such as **Truenat® Scrub T** chip, microtube, microtube cap, pipette tips, Sample pre-treatment tube, Transport Medium for Swab Specimen Tube etc. in freshly prepared 0.5% sodium hypochlorite solution for 30 minutes before disposal as per the standard medical waste disposal guidelines.
2. Disinfect the solutions and/or solid waste containing biological samples before discarding them according to local regulations.
3. Samples and reagents of human and animal origin, as well as contaminated materials, disposables, neutralized acids and other waste materials must be discarded according to local regulations after decontamination by immersion in a freshly prepared 0.5% of sodium hypochlorite for 30 minutes (1 volume of 5% sodium hypochlorite for 10 volumes of contaminated fluid or water).
4. Do not autoclave materials or solutions containing sodium hypochlorite.
5. Chemicals should be handled in accordance with Good Laboratory Practice and disposed off according to the local regulations.

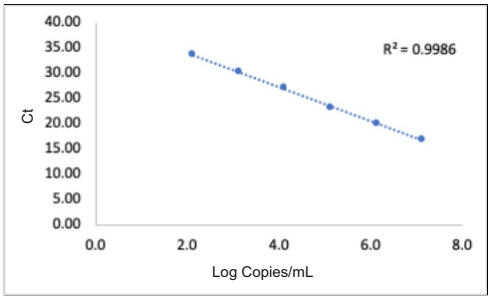
18. SPECIFIC PERFORMANCE CHARACTERISTICS

Analytical Exclusitivity (Primer specificity): The following microorganisms were evaluated *in silico* from the the NCBI database using the NCBI nucleotide blast and primer blast tools to determine for potential cross-reactivity in the **Truenat® Scrub T** assay. No cross reactivity in the performance of the **Truenat® Scrub T** assay was observed with the listed microrganisms.

Candida albicans	Adenovirus
Chlamydia trachomatis	Cytomegalovirus
Enterobacter aerogenes	Hepatitis B Virus
Mycobacterium gordonae	Hepatitis C Virus
Staphylococcus epidermidis	Human Immunodeficiency Virus
Mycobacterium tuberculosis	Epstein-Barr Virus
Escherichia coli	Herpes Simplex Virus-1
Staphylococcus aureus	BK Virus
Neisseria gonorrhoeae	Alphapapillomavirus 7
Klebsiella pneumoniae	Alphapapillomavirus 9
Human DNA (Various Samples)	Human herpes virus 3
Herpes Simplex Virus-2	Human herpes virus 4
Parvovirus	Vaccinia Virus
Human herpes virus 6	Human herpes virus 8

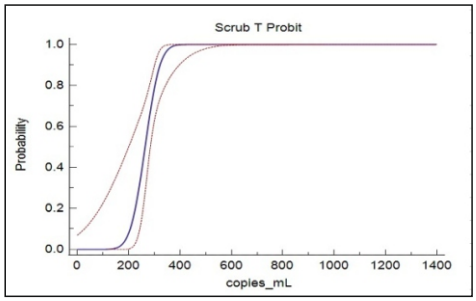
Linearity and Assay range:

The Linearity analysis was performed according to CLSI Guidelines. Serial dilutions of plasmid from 1.37E+07 to 1.37E+02 copies/mL were made and nucleic acids were extracted on **Trueprep® AUTO** Universal Cartridge Based Sample Prep Device in triplicates for each dilution followed by PCR on **Truelab® Uno Dx** Real Time Quantitative micro PCR Analyzer using **Truenat® Scrub T** test. The assay is found to be linear over 6 orders of magnitude (from 1.37E+07 to 1.37E+02 copies/mL) for Scrub Typhus samples obtained from Manipal Institute of Virology.



Limit of detection:

The LoD was determined by making dilutions of cloned and quantified Scrub Typhus sample obtained from Manipal Institute of Virology and performing nucleic acid extractions on **Trueprep® AUTO** Universal Sample Pre-reatment pack. sample prep device for each of the dilution 24 times followed by PCR on **Truelab® Uno Dx** Real Time micro PCR Analyzer. Probit analysis of the data was used to determine the concentration of the DNA with 95% probability of detection. The LoD was found to be 339 copies/mL.



Robustness:

To determine whether the **Truenat® Scrub T** Chip-based Real Time PCR test showed any signs of carryover of PCR products between runs, alternate runs of positive samples and negatives samples were performed. 20 positive and 20 negative samples were used for the study. The **Truenat® Scrub T** test did not exhibit detectable carryover contamination between positive to negative sample runs.

Reproducibility:

The purpose of this study is to compare the functional performance of the **Truenat® Scrub T** assay using three different titres of samples on **Truelab® Uno Dx** Real Time micro PCR analyzer. High, Medium and low titre samples were extracted and tested among three different users (Inter user), on three different devices (Inter device) and on 5 consecutive days (Inter day) to check the variability. Mean %CV values for all titres has been calculated for Inter User (1.71), Inter day (1.61) and Inter Device (1.37) which were in the accepted range of ≤15% CV for **Truenat® Scrub T** assay.

Accuracy of Truenat® Scrub T assay :

Accuracy was determined by performing DNA extractions and **Truenat® Scrub T** PCR for varying titres of samples over 5 consecutive days. The CV values obtained were within the accepted range of ≤15 % CV for **Truenat® Scrub T** assay.

Clinical Validation:

Total 30 samples comprising of 20 negative and 10 positive blood samples were tested on three different lots of **Truenat® Scrub T** assay at AIIMS (All India Institute of Medical Sciences), Raipur, Chhattisgarh against the AIIMS in-house conventional PCR assay.

		Conventional PCR Assay		
		Positive	Negative	Total
Truenat® Scrub T	Positive	10	0	10
	Negative	0	20	20
	Total	10	20	30

With the consideration of above data, **Truenat® Scrub T** performed well in this study with the observed sensitivity of 100% and specificity of 100%.

19. REFERENCES

1. https://www.cdc.gov/typhus/scrub/index.html
2. https:llwww.nhp.gov.inldiseaselscrub-typhus
3. 3. Chakraborty S., Sharma. N. Scrub Typhus: An Emerging Threat. Indian J Dermatol. 2017. 62(5): 478-485.
4. Kala D., Gupta S., Nagraik R., et al., Diagnosis of scrub typhus: recent advancements and challenges. 3 Biotech. 2020. 10:396.
5. Kannan K., John R., Kundu D., et al. Performance of molecular and serologic tests for the diagnosis of scrub typhus. PLOS Neglected Tropical Diseases. 2020: 1-13.
6. Koh W.K.C.G., Maude J.R., Paris H. D.,et a/. Review: Diagnosis of Scrub Typhus. Am. J. Trap. Med. Hyg. 2010. 82(3): 368-370
7. Rapsang G.A., Battacharyya P, Scrub Typhus. Indian J Anaesth. 2013. 57(2):127-134.
8. Saxena S., Khiangte B., Tiewsoh I. Scrub Typhus Complicated by Acute Respiratory Distress Syndrome and Multiorgan Failure; an Unrecognized Alarming Entity in Central India: A Report of Two Cases. J Family Med Prim Care. 2014.3(1): 80-83.
9. Trung V.N., Hai T L., Dien M.V., et al. Clinical Manifestations and Molecular Diagnosis of Scrub Typhus and Murine Typhus, Vietnam, 2015-2017. Emerg Infect Dis.2019.25(4): 633--641.

20. REVISION HISTORY

Section	Description of the changes
Throughout	Symbols are added as per IVDR requirements
1,2,3,7,9,10,14,17	Section is updated
20	Added Revision History table
Symbol keys	Symbol keys are updated

SYMBOL KEYS

Consult instruction for use	IVD *In vitro* Diagnostic Medical Device	LOT Batch number/ Lot number	REF Catalogue number	UDI Unique Device Identifier	This way up	Manufacturer	Caution.	Non sterile.
Contains sufficient for <n> tests	Temperature limitations	Date of manufacture	Date of expiry	For single use only	Keep dry	Keep away from sunlight	Device for near-patient testing	EC REP Authorised Representative in European Community

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