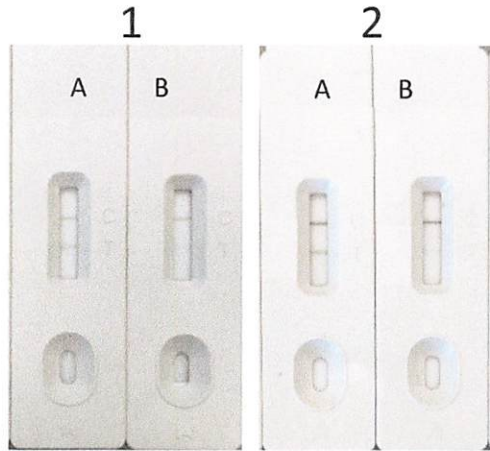


	<p>Drugs & Diagnostics for Tropical Diseases 9909 Huennekens St. Suite 100 San Diego 92121 Phone: 858-614-6454, www.ddtd.org</p>	<p>Document # COA-21-003</p>
<p>NSF International</p>	<p>ISO-13485 Certification #</p>	<p>C0448681</p>

Certificate of Analysis

Detail	
Product Name	Buruli Ulcer RDT
Part No, if available	
Packaging Information	A sealed metalized pouch with 100 individually sealed Buruli Ulcer RDT cassettes, a glass vial with 5 doses of lyophilized magnetic nanoparticles Mag-NS-JD5.1, a dropper vial with chase buffer, all stored at 4°C; 10 µM mycolactone in ethanol for positive control stored at -20 °C.
Quantity	100 cassettes x5 , 20 glass vials with lyophilized Mag-NS-JD5.1 x 5, 2 droppers with 4 ml chase buffer x5, 4 ampoules with 60 ul of 10 µM mycolactone (7ng/µL) in ethanol.
Lot Number	Mag-NS-JD5.1 Lot# MS-2021-272 (lyophilized) NC Strips Lot# MS-2021-269 Assembled cassettes Lot# MS-2021-272 Running buffer Lot# MS-2021-274
Manufacturing Date	April 2021
Expiration Date	October 2021
Storage Condition	4 °C
Test Method	7 ng mycolactone in 50 µL simulated exudate extracted with 400 µL 100 mM TEA buffer or di-H2O, incubated with 50 µL of reconstituted Mag-NS-JD5.1 for 25 min, Mag-NS-JD5.1 were concentrated on magnetic rack for 10 min, resuspended with 2 drops of running buffer, transferred to the sample port of the cassette, read in 30 min.
Test Specification	3 shades difference for the test line intensity between positive and negative sample or 0.05 absorbance units by Leelu reads
Test Results	The difference in test line intensity between positive and negative sample: 3-2.5 shades 0.06-0.37 absorbance by Leelu
Approved or Rejected	
Disclosure	
Copies of the actual testing related documents are provided to the customers upon request.	

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1. ML extracted in 100 mM TEA pH 7.9
2. ML extracted in di-H2O
 - A. negative control - simulated wound exudate (PBS : normal human serum 1:1)
 - B. positive control - simulated wound exudate with 7 ng mycolactone

The undersign confirms that this product meets or exceeds all specifications set forth by the customer in the order.

Name	<i>Marina T. Siirin</i>
Designation	CEO/Quality Manager/Sr. Scientist
Signature/Date	<i>04/30/2021</i>

Document Control			
Action	Date	Signature	Author/Reviewer/Approver
Approved			Dr. Marco Biamonte, CEO
Implemented			
Amendment/Change			