

LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

Mpox Virus DNA, QL PCR

EXAMPLE, REPORT W

WX0000003826 F 12/05/1988 34 Y

Referral Testing						
	Collected: 09/	14/2023	11:45	Received:	09/14/2023	11:45
<u>Test Name</u>	Result	Flag	Ref-Ranges	<u>l</u>	<u>Jnits</u>	<u>Site</u>
Monkeypox Virus DNA, QL RT PCR						
Patient Race:	NA					QCRL
Ethnicity:	NA					QCRL
Specimen Type	LFT HAND					QCRL
Anatomic Location	NA					QCRL
Orthopoxyvirus DNA, QL PCR	DETECTED	AB				QCRL

AB

DETECTED

This specimen is positive for Monkeypox virus (West African clade, Clade II).

REFERENCE RANGE: NOT DETECTED

The Monkeypox Virus DNA Real-time PCR is intended for the qualitative detection of Non-variola Orthopoxviruses and Monkeypox virus (West African clade, Clade II) DNA using swabs from human pustular or vesicular rash specimens. The quality of a clinical sample is evaluated by the presence of human RNase P. If RNase P is Not detected and the target DNA is Not detected then the result is reported is INVALID. These results must be used in conjunction with clinical observations and epidemiological risk factors.

Please review the Fact Sheets and FDA authorized labeling available for health care providers and patients using the following websites:

This test has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories.

Due to the current public health emergency, Quest Diagnostics is accepting samples from appropriate clinical sources (swabs of lesions) collected using a wide variety of swabs and viral transport media for Monkeypox testing, which may not have the equivalent ingredients as the media validated by Quest Diagnostics. Not detected test results derived from specimens received in non-validated media, including non-commercially manufactured viral collection kits, should be cautiously evaluated. Extra precautions should be considered such as additional clinical monitoring and collection of an additional specimen if clinically indicated.

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, $\,$. - NOT TESTED

F314000007 WX0000003826 Printed D&T: 09/14/23 11:46 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

QCRL



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Referral Testing

Collected: 09/14/2023 11:45 Received: 09/14/2023 11:45

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Periodically, Quest Diagnostics may need to modify the authorized test and the modified test will not be reviewed by FDA. For a list of such modifications, supporting data, and additional information please refer to: (This link is being provided for informational/educational purposes only.)

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD

Performing Site:

QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.09.14 11:45 MKPXV

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Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 2