Roche gets EUA for high-throughput monkeypox test

December 2022—Roche announced that the FDA has granted emergency use authorization for the Cobas MPXV for use on Cobas 6800/8800 systems. The real-time PCR test is for the qualitative detection of DNA from monkeypox virus in lesion swabs collected from individuals suspected of having monkeypox infection by their health care provider. The assay uses β-globin as an endogenous control to assess specimen adequacy. It detects monkeypox nucleic acids and the endogenous control in the same well.

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