QUIDEL | QuickVue+

Mononucleosis Test

Frequently Asked Questions

What are the CMS recommended CPT code and National Limit amounts for this kit?
The suggested CPT code is 86308QW.* For the current Medicare National Limit amount** click here.

What is the CLIA complexity of the test?
Serum and plasma are moderately complex and whole blood is CLIA waived.

What is the kit shelf life and storage?
The shelf life is 24 months from the date of manufacture. The kit should be stored at room temperature 59°F to 86°F (15°C to 30°C), out of direct sunlight.

Are there any age limitations with this kit?
No, there are no age limitations with this test kit.

How often should external controls be run on the kit?
Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits – provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.

How long after infection will a patient test positive with this test versus other rapid mono tests?
Most rapid mono tests are designed to detect Infectious Mononucleosis (IM) heterophile antibodies. These antibodies include the IgG and IgM antibodies. During the acute phase of illness, certain heterophile antibodies appear in 85%-90% of IM cases. These IM heterophile antibodies are primarily of the IgM class.[1,2] IgM to the viral capsid antigen appears early in infection and disappears within 4 to 6 weeks. IgG to the viral capsid antigen appears in the acute phase, peaks at 2 to 4 weeks after onset, declines slightly, and then persists for life.[3] With the QuickVue+ Mononucleosis Test, a patient will only test positive for IM when the IgM antibodies are present indicating an early phase infection. With an IM test that detects IgG antibodies, a positive result may be due to a previous mono infection.

Why is the QuickVue+ Mononucleosis Test giving a negative result when other data suggests that the patient has mononucleosis?
A negative result may be obtained from patients at the onset of the disease due to an antibody concentration below the sensitivity of this test kit. If the symptoms persist, the patient should be retested. Some segments of the

[1] Paul J.R. and Bunnell W.W. (1932) Amer. J. Med. Sci. 183:90-104.
[2] Davidsohn I. (1937) J.A.M.A. 108:289-296.
[3] http://www.cdc.gov/ncidod/diseases/ebv.htm, accessed on April 27, 2010.

population who contract infectious mononucleosis do not produce measurable levels of heterophile antibodies. Approximately 50% of children under 4 years of age who have IM may test as IM heterophile antibody negative.[4]

Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels.

**For state by state fee schedule go to www.cms.gov. "QW" modifier is added to report use of CLIA-waived test system(s) for Medicare/Medicaid claims.

FQ20121002EN00 (07/21)

[4] Fleisher, G.R. (1984) In Belshe, R.B. (ed.): Textbook of Human Virology. Littleton, Mass., PSG Publishing Co., pp 853-886.