3/24/2014 - New Release, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	**Test Name**	**Effective Date**	**Page #**
92074	**Calreticulin (CALR) Mutation Analysis**	3/31/2014	1

New Test Offering

The following tests will be available through Quest Diagnostics on the dates indicated below.

Calreticulin (CALR) Mutation Analysis	
Message	***This test is not available for New York patient testing.***
Clinical Significance	**Calreticulin (CALR) mutations have been reported in 50-71% of essential thrombocythemia (ET), and 56-88% of primary myelofibrosis (PMF) that are negative for JAK2 and MPL mutations. ET and PMF with CALR mutations are associated with distinct clinical features and can have superior outcome to MPL-mutated and JAK2-mutated ET and PMF in initial studies. Testing for this mutation can assist in the diagnosis of myeloproliferative neoplasms, and provide a marker for monitoring response to therapy and disease recurrence.**
Effective Date	**3/31/2014**
Test Code	**92074**
CPT Codes	**81479**
Specimen Requirements	**Preferred:** **5 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube** **Acceptable:** **Whole blood collected in a sodium heparin (green-top) tube or sodium citrate (light blue-top) tube** **1 mL (0.5 mL minimum) bone marrow aspirate collected in an EDTA (lavender-top) tube** **Formalin fixed, paraffin-embedded tissue block** **10 slides (4 slide minimum) of formalin fixed, paraffin-embedded tissue** **Fixed cell pellets from cytogenetic preparations** **Other sample types, call lab. Do Not Reject**.
Reject Criteria	**Gross hemolysis**
Transport Temperature	**Room temperature**
Specimen Stability	**Whole blood, Bone marrow and Fixed cell pellet** — **Room temperature and Refrigerated: 7 days** **Frozen: Unacceptable** **Slides and Formalin fixed, paraffin embedded tissue block:** — **Room temperature and Refrigerated: Indefinite** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 5 days**
Reference Range	**CALR Mutation (exon 9): Not detected** **Mutation Site: No reference range available**
Always Message	**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.** **For more information on this test, go to:** **http://education.questdiagnostics.com/faq/FAQ140**

The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

Methodology	**Polymerase Chain Reaction (PCR) Sequencing**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Type	Result Name
86007404	**Prompt-Result**	**Specimen Source:**
86007476	**Prompt-Result**	**Block ID:**
86006921	**Prompt-Result**	**Clinical Indication:**
86010670		**CALR Mutation (exon 9):**
86010671		**Mutation Site:**
86010672		**Interpretation:**

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