ACL Laboratories
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Test Bulletin

November 2019

ACL Laboratories Changes Methodology for Trace Metal Testing

Effective immediately, ACL Laboratories is performing testing for trace metals using an improved methodology, Inductively Coupled Plasma Mass Spectrometry or ICP-MS. ICP-MS is a highly sensitive analytical technique that is widely used for metal testing and is considered the method of choice for numerous reasons. ICP-MS offers lower detection limits than the prior methodology and has minimal matrix interferences. In addition, throughput is enhanced due to automation and the ability to simultaneously measure more than one element at a time.

The following tests are currently performed using ICP-MS:

Test Order Code	Test Name
ARSN	Arsenic, Blood
UAS	Arsenic, Urine
UASOC	Arsenic, Urine Occupational
UCADM	Cadmium, Urine
UCADOC	Cadmium, Urine Occupational
CU	Copper, Blood
HG	Mercury, Blood
UHG	Mercury, Urine
PBVEN	Lead Blood Venous
PBCAP	Lead, Blood Capillary
UPBU	Lead, Urine
ZN	Zinc

Please note:

- There are ***no*** changes in specimen collection requirements.
- There are ***no*** changes in reference ranges for any of the analytes.
- Testing will continue to be performed according to the current listing in ACL's Directory of Services.

For additional information, please contact ACL Client Services at 1-800-877-7016 or visit our website at www.acllaboratories.com/test-catalog/.

2020 CPT Code Changes

ACL Test Order Code	Test Description	2019 CPT Code(s)	2020 CPT Code(s)
ADALIM	Adalimumab Concentration and Anti-Adalimumab Antibody	80299 82397	80145 82397
POSACN	Posaconazole	80299	80187
INFLIX	Infliximab Concentration and Anti-Infliximab Antibody	80299 82397	80230 82397
LACOSA	Lacosamide	80339	80235
VEDOLZ	Vedolizumab and Anti-Vedolizumab Antibody	80299 82397	80280 82397
VORIC	Voriconazole	80299	80285
SWOEXT	SwabOne Extended Vaginitis Panel	87481 x3 87661 87798 x3 87801	87481 x3 87661 87798 x2 87563 87801
SWOMU	SwabOne MYC/Ureaplasma Panel	87798 x3	87798 x2 87563
SWOMG	SwabOne Mycoplasma Genitalium	87798	87563

ACL Laboratories Announces Changes in Instrument Platform for Free Kappa and Free Lambda Light Chains

Effective immediately, ACL Laboratories changed the platform for Kappa and Lambda Free Light Chain testing to The Binding Site Optilite instrument. The Free light chains assay and reagents, Freelite, will ***not*** change.

Testing is currently performed on the Beckman Immage using Freelite reagents purchased from The Binding Site. The Binding Site has discontinued production of reagents for this application, necessitating the change.

Specimen collection, handling and processing, and reference ranges **will remain the same**:

Kappa Free Light Chain:	0.33-1.94 mg/dL
Lambda Free Light Chain:	0.57-2.63 mg/dL
Kappa/Lambda FLC Ratio:	0.26-1.65

Key considerations regarding this change:

- Freelite Reagents used for the new instrument are the same ones currently used on the former platform.
- The Binding Site Freelite assay is the ***only*** FDA cleared free light chain assay available.
- 96% of laboratories use Freelite for testing and the majority perform testing on the Optilite instrument.
- Freelite is the only method referenced by the International Myeloma Working Group (IMWG) for diagnosis and monitoring of disease.

Although ACL does not believe re-baselining of patients is necessary, the decision to do so is at the discretion of the Provider. During ACL's method validation, we did not see significant differences in patient results between the two methods. Additionally, test results must be interpreted in conjunction with other laboratory and clinical findings.

All results will be reported with the following comment to notify ordering Providers of this change:

> "Test methodology changed from Beckman Immage to The Binding Site Optilite Effective September 30, 2019. There is no anticipated change in reference intervals. In some patients, re-baselining may be necessary if clinically indicated."

For additional information, please contact ACL Client Services at 1-800-877-7016 or visit our website at www.acllaboratories.com/test-catalog/

Additional Information on Free Light Chain Testing:

Clinical Indications:

1. Initial evaluation of suspected myeloma.
2. Monitoring myeloma and amyloidosis. The quantitation of the monoclonal light chain is useful for monitoring disease activity

Multiple myeloma and other monoclonal gammopathies represent a family of disorders characterized by the proliferation of a monoclonal population of plasma cells and the production of a monoclonal immunoglobulin protein.

All monoclonal myeloma cells secrete excess free light chains (either Kappa or lambda sub-types).

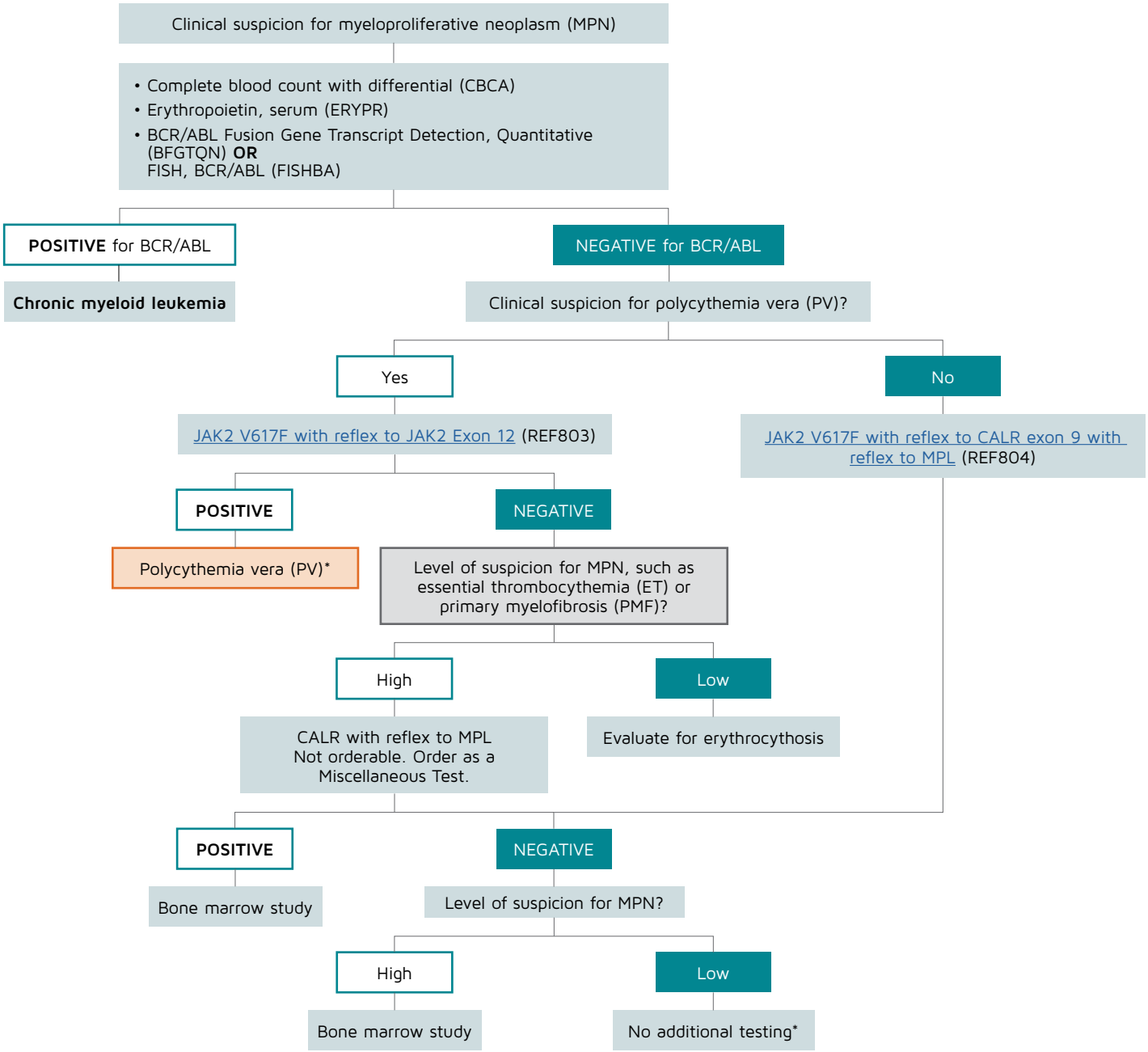
- Increased kappa free light chains and an increased kappa/lambda ratio may be seen with plasma cell disorders that produce excess monoclonal kappa light chains.
- Increased lambda free light chains and a decreased kappa/lambda ratio may be seen with plasma cell disorders that produce excess monoclonal lambda light chains.
- decrease in the quantity of excess light chain and a more normal kappa/lambda ratio may indicate a response to treatment.

Serum free light chain (FLC) Indications:

1. Measures concentration of monoclonal free light chains produced.
2. Results of a serum free light chain test will often be evaluated in conjunction with the results of a protein electrophoresis test.
3. Detects abnormal ratios of free light chains in the serum. Abnormalities of the free light chain ratio (kappa/lambda) provide a more sensitive indication of monoclonal disease than simple elevations of one light chain.
4. Changes in FLC quantitation reflect changes in the size of the monoclonal plasma cell population. Generally, changes of >25% or trending of multiple specimens are needed to conclude biological significance.
5. It is not recommended that serum free light chains are ordered to assess for multiple myeloma or light chain disease in the setting of inflammatory conditions or renal insufficiency.
6. This test must be interpreted in conjunction with other laboratory and clinical findings. A slightly abnormal result does not prove that someone has a plasma cell disorder. Conversely, someone may have a plasma cell disorder despite a normal result from this test.

In an effort to provide our clients with educational resources to aid in appropriate test ordering, ACL has developed a diagnostic algorithm for myeloproliferative neoplasms (MPNs). This algorithm aims to reduce the time to diagnosis by employing reflex assays for genetic testing, which also allows for more cost-effective ordering and reduces unnecessary phlebotomy draws. Please note that each step of the algorithm is physician driven; based on results at each step, please place a new order as appropriate. For ease of reference, the current World Health Organization diagnostic criteria for polycythemia vera, essential thrombocythemia, and primary myelofibrosis are included.

Our MPN algorithm can be accessed by clicking here or through various Directory of Services test entries, such as JAK2B, CALR, REF803, and REF804.



If you have any questions, please consult the ACL Laboratories Directory of Services at https://www.acllaboratories.com/test-catalog/ or contact our ACL genetic counselors with any clinical questions by calling 847-349-7440.