Test Definition: PEL

Electrophoresis, Protein, Serum

Overview

Useful For

Monitoring patients with monoclonal gammopathies

Diagnosis of monoclonal gammopathies

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
TPE	Total Protein	Yes, (order TP)	Yes
ELP	Protein Electrophoresis	No	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
IMFX	Immunofixation	No	No
IFXED	Immunofixation Delta and Epsilon, S	Yes	No

Testing Algorithm

If a discrete electrophoresis band is identified, the laboratory will evaluate the serum protein electrophoresis and, if necessary, perform immunofixation at an additional charge.

If a monoclonal light chain is detected in the absence of an associated monoclonal heavy chain, an immunofixation electrophoresis (IFE), specific for delta and epsilon chains, is performed at an additional charge.

If patient history indicates the presence of a previously identified monoclonal heavy chain, specific for delta and epsilon, monoclonal IFE specific for delta and epsilon chains is performed at an additional charge.

Method Name

TPE: Colorimetric, Biuret
ELP: Agarose Gel Electrophoresis
IMFX, IFXED: Immunofixation

NY State Available

No

Specimen

Specimen Type

Serum

Necessary Information

Indicate if multiple myeloma is suspected.

Specimen Required

Patient Preparation: Fasting 12 hours, preferred but not required
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume:1 mL
Collection Instructions: Centrifuge and aliquot serum into plastic vial within 2 hours of collection.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Ambient	14 days	
	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Serum proteins can be grouped into 5 fractions by protein electrophoresis:
-Albumin, which represents almost two-thirds of the total serum protein
-Alpha-1, composed primarily of alpha-1-antitrypsin (A1AT), an alpha-1-acid glycoprotein
-Alpha-2, composed primarily of alpha-2-macroglobulin and haptoglobin
-Beta, composed primarily of transferrin and C3
-Gamma, composed primarily of immunoglobulins

The concentration of these fractions and the electrophoretic pattern may be characteristic of diseases such as monoclonal gammopathies, A1AT deficiency disease, nephrotic syndrome, and inflammatory processes associated with infection, liver disease, and autoimmune diseases.

Reference Values

PROTEIN, TOTAL
> or =1 year: 6.3-7.9 g/dL
Reference values have not been established for patients that are younger than 12 months of age.

PROTEIN ELECTROPHORESIS
Albumin: 3.4-4.7 g/dL
Alpha-1-globulin: 0.1-0.3 g/dL
Alpha-2-globulin: 0.6-1.0 g/dL
Beta-globulin: 0.7-1.2 g/dL
Gamma-globulin: 0.6-1.6 g/dL
An interpretive comment is provided with the report.
Reference values have not been established for patients that are younger than 16 years of age.

Interpretation

Monoclonal Gammopathies:
-A characteristic monoclonal band (M spike) is often found on protein electrophoresis (PEL) in the gamma-globulin region and more rarely in the beta or alpha-2 regions. The finding of a M-spike, restricted migration, or hypogammaglobulinemic PEL pattern is suggestive of a possible monoclonal protein and should be followed by MPSU / Monoclonal Protein Study, 24 Hour, Urine, which includes immunofixation (IF), to identify the immunoglobulin heavy chain and/or light chain.
-A monoclonal IgG or IgA greater than 3 g/dL is consistent with multiple myeloma (MM).
-A monoclonal IgG or IgA less than 3 g/dL may be consistent with monoclonal gammopathy of undetermined significance (MGUS), primary systemic amyloidosis, early or treated myeloma, as well as a number of other monoclonal gammopathies.
-A monoclonal IgM greater than 3 g/dL is consistent with macroglobulinemia.
-The initial identification of a serum M-spike greater than 1.5 g/dL on PEL should be followed by MPSU / Monoclonal Protein Study, 24 Hour, Urine.
-The initial identification of an IgM, IgA, or IgG M-spike greater than 4 g/dL, greater than 5 g/dL, and greater than 6 g/dL, respectively, should be followed by SVISC / Viscosity, Serum.
-After the initial identification of an M-spike, quantitation of the M-spike on follow-up PEL can be used to monitor the monoclonal gammopathy. However, if the monoclonal protein falls within the beta region (most commonly an IgA or an IgM), quantitative immunoglobulin levels may be a more useful tool to follow the monoclonal protein level than PEL. A decrease or increase of the M-spike that is greater than 0.5 g/dL is considered a significant change.
-Patients suspected of having a monoclonal gammopathy may have normal serum PEL patterns. Approximately 11% of patients with MM have a completely normal serum PEL, with the monoclonal protein only identified by IF. Approximately 8% of MM patients have hypogammaglobulinemia without a quantifiable M-spike on PEL but identified by IF. Accordingly, a normal serum PEL does not rule out the disease and should not be used to screen for the disorder. The MPSS / Monoclonal Protein Study, Serum, which includes immunofixation, and FLCS / Immunoglobulin Free Light Chains, Serum should be done to screen if the clinical suspicion is high.

Other Abnormal PEL Findings:
-A qualitatively normal but elevated gamma fraction (polyclonal hypergammaglobulinemia) is consistent with infection, liver disease, or autoimmune disease.
-A depressed gamma fraction (hypogammaglobulinemia) is consistent with immune deficiency and can also be

associated with primary amyloidosis or nephrotic syndrome.
-A decreased albumin (<2 g/dL), increased alpha-2 fraction (>1.1 g/dL), and decreased gamma fraction (<1 g/dL) is consistent with nephrotic syndrome, and when seen in an adult older than 40 years, should be followed by MPSU / Monoclonal Protein Study, 24 Hour, Urine.
-In the hereditary deficiency of a protein (eg, agammaglobulinemia, alpha-1-antitrypsin [A1AT] deficiency, hypoalbuminemia), the affected fraction is faint or absent.
-An absent alpha-1 fraction is consistent with A1AT deficiency disease and should be followed by a quantitative A1AT assay (AAT / Alpha-1-Antitrypsin, Serum).

Cautions

A normal serum protein electrophoresis does not rule-out disease. MPSS / Monoclonal Protein Study, Serum, which includes immunofixation, and FLCS / Immunoglobulin Free Light Chains, Serum should be done to screen if the clinical suspicion is high.

Very large IgG M-spikes (>4 g/dL) may saturate the protein stain. In these situations, quantitative IgG assays (IGG / Immunoglobulin G [IgG], Serum) should be performed to accurately determine M-spike concentrations to monitor disease progression or response to therapy.

Fibrinogen will migrate as a distinct band in the beta-gamma fraction. Serum specimens from new patients with a beta-gamma band are to be treated with thrombin to ensure complete conversion of fibrinogen.

Hemolysis may augment the beta fraction.

Penicillin may split the albumin band.

Radiographic agents may produce an uninterpretable pattern.

Clinical Reference

1. Sykes E, Posey Y: Immunochemical characterization of immunoglobulins in serum, urine, and cerebrospinal fluid. In: Detrick B, Schmitz JL, Hamilton RG, eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. ASM Press; 2016:89-100
2. Katzmann JA, Keren DF: Strategy for detecting and following monoclonal gammopathies. In: Detrick B, Schmitz JL, Hamilton RG, eds. Manual of Molecular and Clinical Laboratory Immunology. 8th ed. ASM Press; 2016:112-124
3. Kyle RA, Katzmann JA, Lust JA, Dispenzieri A: Clinical indications and applications of electrophoresis and immunofixation. In: Rose NR, Hamilton RG, Detrick B, eds. Manual of Clinical Laboratory Immunology. 6th ed. ASM Press; 2002:66-70

Performance

Method Description

Total Protein:
Divalent copper reacts in alkaline solution with protein peptide bonds to form the characteristic purple-colored biuret complex. Sodium potassium tartrate prevents the precipitation of copper hydroxide and potassium iodide prevents autoreduction of copper. The color intensity is directly proportional to the protein concentration which can be

determined photometrically.(Package insert: TP2 cobas. Roche Diagnostics; V 12.0. 11/2019)

Electrophoresis:
Serum proteins are separated in an electric field according to their size, shape, and electric charge. The separation is performed on agarose gels. The proteins are visualized by staining with acid blue and the intensity of staining is quantitated by densitometry. Multiplying by the serum total protein converts the percentage of protein in each fraction into serum concentration.(Instruction manual: Helena Spife Touch, Helena Laboratories, Corp; 11/2016; package insert: Helena Spife Touch SPE, Helena Laboratories, Corp; 06/2018;)

Immunofixation:
Immunofixation is performed with Sebia reagent sets and are specific for gamma, alpha, mu, kappa, and lambda immunoglobulin heavy and light chains.(Package insert: Sebia Hydrasys Hydragel 1, 2, 4, and 9IF. Sebia, Inc; 09/2015)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
1 to 6 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Jacksonville Clinical Lab

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
84155
84165
86334-Immunofixation (if appropriate)

86334-Immunofixation Delta and Epsilon (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PEL	Electrophoresis, Protein, S	24351-9

Result ID	Test Result Name	Result LOINC® Value
TPE	Total Protein	2885-2
2769	Albumin	2862-1
2770	Alpha-1 Globulin	2865-4
2771	Alpha-2 Globulin	2868-8
2773	Beta-Globulin	2871-2
2774	Gamma-Globulin	2874-6
2785	A/G Ratio	44429-9
22308	M spike	33358-3
22309	M spike	33358-3
15254	Impression	49296-7