Test Name	Test Code	Effective Date

BIOREFERENCE IS AN IN-NETWORK CONTRACTED LABORATORY PROVIDER WITH EMBLEMHEALTH

BioReference is pleased to announce a new laboratory services contract with EmblemHealth, Inc. in the New York City metropolitan region. The contract is inclusive of all EmblemHealth health plans and is effective January 1, 2024.

With over 3 million members in the New York tristate area, this new agreement will afford healthcare providers additional options when ordering laboratory testing, and increase access to laboratory services for EmblemHealth members.

If you have any questions regarding the new EmblemHealth status, please feel free to contact our Market Access team at PayRelOperations@bioreference.com.

Test Name	Test Code	Effective Date
NTQR Program Closure	**3268**	**2/15/24**

Please be advised that The Perinatal Quality Foundation (PQF) including the Nuchal Translucency Quality Review (NTQR) program closed at the end of 2023.

In 2002, the Perinatal Quality Foundation established the Nuchal Translucency Quality Program (NTQR). The purpose of this program was to maintain the accuracy and reproducibility of nuchal translucency measurements and nasal bone assessments. The UK based Fetal Medicine Foundation (FMF) fulfills a similar role. Over the years since 2002, our policy at BioReference/GenPath has been to adhere carefully to the NTQR and FMF guidelines by requiring sonographers to supply evidence of their NTQR or FMF certification in order to use their submitted ultrasound data to generate risk results. We believe that compliance with these guidelines is essential for accurate risk reporting. However, as of December 2023, the Perinatal Quality Foundation, including the NTQR no longer exists. Sonographers who have heretofore been credentialed through NTQR, no longer have a quality maintenance program, unless they register with the FMF program.

BioReference/GenPath will continue to accept NTQR numbers through the end of 2024 at which time we will require that sonographers be credentialed through the Fetal Medicine Foundation (FMF). New sonographers needing credentialing in 2024 will have to do so through the FMF.

If you or your practice will be using combined risk assessment (test codes listed below) please direct your sonographers to the Fetal Medicine Foundation (FMF Foundation) to apply for FMF NT credentialing.

Test Code	Test Name
8602	Sequential Screen Part 1 (NT, Total BHCG, PAPP-A)
8622	Combined First Plus (NT, Total BHCG, Inhibin-A, PAPP-A)
6246	Combined First (NT, Total BHCG, PAPP-A)
6375	Integrated Part 1 (NT, PAPP-A)

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Test Name	Test Code	Effective Date
Screening PSA	**3268**	**2/15/24**

In an effort to standardize laboratory practices across all BioReference locations, **Screening PSA (test code 3268)** has been retired. When this test code is ordered, the code will be replaced with **PSA Total (test code 0190-9).** There are no changes in methodology, specimen type, specimen collection, etc.

	Previous Test Information	New Test Information
Primary Container	SST	SST
Minimum Volume		1 mL
Turn Around Time*	1 Day	1 Day
Transportation Temp	Refrigerate	Refrigerate
Stability	3 days	3 days
Methodology	Electrochemiluminescence Immunoassay	Electrochemiluminescence Immunoassay
Reference Range		
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes
Profile Components	n/a	n/a
CPT Code(s)**	84153	84153
Clinical Utility (If applicable)		Prostate specific antigen, produced by the prostate gland, is most useful for monitoring patients for residual disease after radical prostatectomy. PSA values should be <0.05 ng/mL if the entire prostate has been removed. PSA levels above 4 but less than 10 ng/mL are considered to be in the "grey zone". Elevations of PSA may indicate prostate cancer or could be the result of an infection or benign prostate enlargement. Also, refer to test codes J264 and K135 for PSA that reflexes to The 4Kscore Test when age-appropriate total PSA levels are reached (PSA ≥ 2 ng/mL for men aged 45-54, PSA ≥ 3 ng/mL for men aged 55-75, and PSA ≥ 4 ng/mL for men aged ≥ 76 years).

Test Name	Test Code	Effective Date
10-Color Flow Cytometry	**Various**	**Immediately**

Effective immediately, we have implemented an update aimed at improving the readability of our Flow Cytometry Reports. Specifically, we have removed the table in the results section displaying individual percentages for each flow marker. This adjustment is aligned with the understanding that flow data is more effectively interpreted based on patterns rather than the percentage of each marker. Our internal pathologists have confirmed that this modification aligns with industry best practices and will contribute to a clearer, more concise representation of flow cytometry data.

Cont. on page 3

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Test Name	Test Code	Effective Date

10-COLOR FLOW CYTOMETRY ANALYSIS FOR LYMPHOPROLIFERATIVE NEOPLASMS

INTERPRETATION

LYMPH NODE:
- B-cell lymphoma, CD5-/CD10-.
See comments.

COMMENT

The immunophenotype of clonal B-cells is not specific (CD5 and CD10 are negative). Diagnostic considerations include (but are not limited to) marginal zone lymphoma (MZL). Lack of CD5 and CD10 excludes the diagnosis of typical B-small lymphocytic lymphoma (SLL/CLL), CD5-positive mantle cell lymphoma (MCL), Burkitt lymphoma (BL) or follicular lymphoma (FL). Low forward scatter does not favor DLBCL.

Based on the nonspecific phenotype revealed by flow c ostic considerations include (but are not limited to) marginal zone lymphoma (MZL). Clonal B-cells in anal w forward scatter, which favors low-grade lymphoma and does not favor diffuse large B-cell lymphoma, but h define this. Rare cases of CD5-negative MCL or CD10-negative FL cannot be excluded.

NEW

Correlation with morphologic analysis of original tissue section with immunohistochemistry, is recommended for final diagnosis, grading, and subclassification.

GROSS DESCRIPTION

Received fresh in RPMI media soft tissue measuring 1.5 x 0.8 x 0.2 cm. A touch imprint is made. Tissue is prepared for Flow Cytometry.

IMMUNOPHENOTYPIC ANALYSIS

Viability 7AAD: 44.80%
Monoclonal B-cell population (kappa+) without expression of CD5 or CD10 (25.98%). The expression of both sIg and CD20 is moderate. The forward scatter of clonal B-cells is low.
The T-cells (11.85% of total) do not display an aberrant phenotype.

ASSOCIATED TESTS

Fluorescence In-Situ Hybridization (FISH)
Cytogenetics

10-COLOR FLOW CYTOMETRY ANALYSIS FOR LYMPHOPROLIFERATIVE NEOPLASMS

INTERPRETATION

BONE MARROW ASPIRATE:
A B-cell lymphoma exhibiting CD5 expression is detected. Based on the flow cytometry findings, diagnostic considerations include mantle cell lymphoma (MCL, 74% of cellularity).
- Phenotype: lambda+, CD5+, CD23-, CD20+ (moderate to bright), CD200- and CD10-.
See comments.

COMMENT

Please see the Bone Marrow Morphology Analysis report for correlative diagnosis and comment.

IMMUNOPHENOTYPIC ANALYSIS

OLD

Percentage of Abnormal Cells: 74% B-cells Cell Size: AAD: 99.55%
- A monoclonal B-cell population (lambda-positive) expressing CD5 is detected. CD23 and CD200 are negative. The expression of CD20 is moderate to bright. CD38 is brightly expressed. There is no CD11c, CD25, or CD103.
T-cells (0.5%) are unremarkable.

RESULTS

Antibody	Description	Result	Antibody	Description	Result
B-Cell Associated			T-Cell Associated		
CD19	Pan B-cell antigen	65.46%	CD2	Thymic and peripheral T-cells, NK cells	3.97%
CD20	Pan B-cell antigen	75.19%			
CD10	Follicle center B-cells, CALLA, myeloid subset	0.04%	CD3	Pan T-cell antigen, TCR-epsilon subunit	2.44%
CD11c	Monocytes, myeloid subset, hairy cell leukemia	2.35%	CD4	Helper T-cells, thymocyte subset, monocytes	1.73%
CD23	Mature B-cells, CLL	0.03%	CD5	Pan T-cells, mature B-cell subset (B1a cells)	4.86%
CD22	Pan B-cell antigen	77.63%			
CD25	Activated T and B-cells, hairy cell leukemia	34.76%	CD7	Thymic and peripheral T-cells, NK cells	5.66%
CD71	Transferrin receptor, activation antigen	26.38%	CD8	Suppressor T-cells, NK cells, thymocyte subset	1.37%
CD81	B-Cells	66.33%	CD26	Dipeptidyl peptidase IV. Lost in Sezary cells	1.66%
CD103	Activated cells, hairy cell leukemia	0.41%	CD30	Activation Antigen; Reed-Sternberg cells, ALCL (Ki-1)	2%
CD200	B-Cells	1.53%			
Kappa	Kappa Ig light chain, B-cells, plasma cells	0.3%	CD52	Lymphocytes, monocytes, CAMPATH antigen	2.29%
Lambda	Lambda Ig light chain, B-cells, plasma cells	67.74%	TCRa/ß	T-cell receptor heterodimer complex, major T-cell subset	0.09%

ASSOCIATED TESTS

Bone marrow morphology, Immunohistochemistry, FISH, NGS

Please contact your account executive to see a copy of the updated report.

Test Name	Test Code	Effective Date
Immature Granulocytes	**0053-9**	**1/22/2024**

Due to an update in testing platform, the reference ranges for **Immature Granulocytes (test code 0053-9)** have been updated. Please refer to the table below for details.

	Previous Test Information	New Test Information
Reference Range (Units %)	0-1 w (0.0-1.9) 2-3 w (0.0-1.3) 4-12 w (0.0-0.9) 13-25 w (0.0-0.5) 6-23 m (0.0-0.3) 2-5 y (0.0-0.3) 6-11 y (0.0-0.3) 12-17 y (0.0-0.3) >/=18 y (0.0-1.0)	0-2 d (0.0-1.7) 3-13 d (0.0-1.9) 2-3 w (0.0-1.3) 4-12 w (0.0-0.9) 13-25 w (0.0-0.5) 6-23 m (0.0-0.9) 2-5 y (0.0-0.8) 6-11 y (0.0-0.3) 12-17 y (0.0-0.3) >/=18y (0.0-1.0)

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Test Name	Test Code	Effective Date
Potassium, Serum	**0129-7**	**Immediately**

With the arrival of colder weather, the handling of blood specimens to avoid any adverse effects associated with exposure to cold temperatures, is once again a concern that could affect patient care.

Serum potassium is one example of a test that is highly sensitive to extremes in temperature. Spurious elevations to serum potassium will be seen when RBCs rupture due to exposure to cold temperatures. An increase in serum potassium above the normal range of 5.5 mmol/L can easily occur when RBCs, which contain almost 20 times the amount of potassium found in serum, rupture when exposed to severe drops in the ambient temperature.

Proper collection of blood specimens is essential for accurate assessment of various analytes in serum, plasma and whole blood. In particular, serum separator tubes (i.e. SSTs), must be allowed to clot thoroughly followed by adequate centrifugation.

Test Name	Test Code	Effective Date
Prothrombin Time	**0137**	**1/8/2024**

In an effort to standardize laboratory practices, we are implementing changes to the **PT/INR (test code 0137)** reporting format from 2 decimal places to 1 decimal place for the **Burbank** laboratory. See table below for the updated reporting comments.

	Previous Test Information	New Test Information
Reference Range: INR (Int'l Normalized Ratio)	Current reference range for INR is 0.92-1.12 sec	New reference range for INR will be 0.9 to 1.1 sec
Reporting Comments:	Prophylaxis or treatment of venous thrombosis, systemic embolization, and pulmonary embolus 2.00-3.00 sec High-risk patients with mechanical heart valves 2.50-3.50 sec Normal Non-Medicated Patients 0.92-1.12 sec	Moderate intensity therapeutic range: 2.0-3.0 sec (Prophylaxis and Thrombosis) High intensity therapeutic range: 2.5-3.5 sec (Mechanical Prosthetic Valves)

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