MAYO CLINIC LABORATORIES

Test Definition: BCGRV

Immunoglobulin Gene Rearrangement, PCR, Varies

Overview

Useful For

Determining whether a B-cell or plasma cell population is polyclonal or monoclonal in specimens other than blood or bone marrow

Identifying neoplastic cells as having B-cell or plasma cell differentiation

Monitoring for a persistent neoplasm by detecting an immunoglobulin gene rearrangement profile similar to one from a previous neoplastic specimen

Testing Algorithm

The following algorithms are available:

Gastric MALT Lymphoma Diagnostic Algorithm

Gastric MALT Posttherapy Follow-up Algorithm

Special Instructions

- Hematopathology Patient Information
- Gastric MALT Posttherapy Follow-up Algorithm
- Gastric MALT Lymphoma Diagnostic Algorithm

Method Name

Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Varies

Shipping Instructions

Body fluid or spinal fluid must arrive within 4 days of collection.

Specimen Required

Submit only 1 of the following specimens:

Preferred:

Specimen Type: Paraffin-embedded tissue

Container/Tube: Paraffin block
Collection Instructions:
1. Decalcified specimens (eg, bone marrow core biopsies) are **not acceptable**.
2. Indicate specimen source.
3. Include pathology report.
Specimen Stability Information: Ambient
Additional Information: If the quality of the biopsy specimen is poor, testing should not be ordered. Testing may be canceled if DNA requirements are inadequate.

Acceptable:
Specimen Type: Tissue slide
Slides: 20 unstained slides
Container/ Tube: Transport in plastic slide holders.
Collection Instructions:
1. Send 20 unstained, nonbaked slides with 5-micron thick sections of tissue.
2. Decalcified specimens (eg, bone marrow core biopsies) are **not acceptable**.
3. Indicate specimen source.
4. Include pathology report.
Specimen Stability Information: Ambient
Additional Information: Testing may be canceled if resultant extracted DNA does not meet concentration requirements.

Specimen Type: Body fluid
Sources: Pleural, peritoneal, vitreous, and spinal fluid (CSF)
Container/Tube: Sterile container
Specimen Volume: At least 5 mL
Collection Instructions:
1. If the volume is greater than 5 mL, pellet cells and then store and send refrigerated.
2. Specify the type of fluid being submitted.
Specimen Stability Information: Refrigerate (preferred)/Ambient 4 days

Specimen Type: Frozen tissue
Container/Tube: Plastic container
Specimen Volume: 100 mg
Collection Instructions:
1. Freeze tissue within 1 hour of collection.
2. Indicate specimen source.
Specimen Stability Information: Frozen

Specimen Type: Extracted DNA
Container/Tube: 1.5- to 2-mL tube
Specimen Volume: Entire specimen
Collection Instructions:
1. DNA must be extracted within 7 days after collection.
2. Label specimen as extracted DNA and source of specimen.

3. Provide volume and concentration of DNA.

Specimen Stability Information: Frozen (preferred)/Refrigerated/Ambient

Additional Information: DNA must be extracted in a CLIA-certified laboratory or equivalent and must be extracted from a specimen type listed as acceptable for this test (including applicable anticoagulants). We cannot guarantee that all extraction methods are compatible with this test. If testing fails, one repeat will be attempted, and if unsuccessful, the test will be reported as failed and a charge will be applied.

Forms

1. Hematopathology Patient Information (T676)
2. If not ordering electronically, complete, print, and send a Hematopathology/Cytogenetics Test Request (T726) with the specimen.

Specimen Minimum Volume

Body Fluid: 1 mL; Frozen tissue: 50 mg; Extracted DNA: 50 microliters (mcL) at 20 ng/mcL; Tissue slides: 10 unstained slides

Reject Due To

Bone marrow core biopsies	Reject
Paraffin shavings	Reject
Broken or cracked unstained slides	Reject
Frozen body fluid	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Varies		

Clinical & Interpretive

Clinical Information

The immunoglobulin genes (heavy, kappa, and lambda) are comprised of numerous, discontinuous coding segments. As B cells develop, the segments are rearranged such that each mature B cell or plasma cell has a unique rearrangement profile. Other cell types usually retain unrearranged gene structures. Clonal expansion of any B cell or plasma cell will result in a population of cells that all contain identical immunoglobulin gene rearrangement profiles.

Reactive B-cell or plasma cell expansions are polyclonal, with each clone containing relatively few cells and no single

clone predominating. Conversely, neoplastic clones are generally large such that the clonal cells are the predominant B cells or plasma cells present.

In the appropriate clinical and pathologic setting, detection of a prominent immunoglobulin gene rearrangement profile may be equated to the presence of a neoplastic B-cell or plasma cell clone.

Reference Values

An interpretive report will be provided.

Interpretation

Results will be characterized as positive, negative, or indeterminate for a clonal B-cell population and include an interpretive report.

The interpretation of the presence or absence of a predominant immunoglobulin gene rearrangement profile is sometimes subjective. These results must always be interpreted in the context of other clinicopathologic information to determine the significance of the result.

The detection of a clonal immunoglobulin gene rearrangement by this test is not synonymous with the presence of a B-cell or plasma cell neoplasm.

Cautions

This test is neither 100% sensitive nor 100% specific.

False-negative results may occur if the immunoglobulin gene has numerous point alterations introduced during expansion in a follicle center (somatic hypermutation) such that none of the polymerase chain reaction (PCR) primers will bind. False-negative results will also occur if the clonal cells have not rearranged the immunoglobulin genes being evaluated or are present below the sensitivity level of the assay (sensitivity is quite variable but the assay requires that at least 1% to 5% of the nucleated cells present be clonal). False-positive results are rare but may occur if a predominant clone (or small number of clones) is produced or sampled from a polyclonal expansion.

The test does not provide information regarding:
-The differentiation of the clonal cell population (neoplastic cells other than B cells or plasma cells may occasionally have immunoglobulin gene rearrangements)
-Whether a prominent clone is physiologic or neoplastic

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Clinical Reference

1. van Dongen JJ, Langerak AW, Bruggemann M, et al. Design and standardization of PCR primers and protocols for detection of clonal immunoglobulin and T-cell receptor gene recombinations in suspect lymphoproliferations: report of the BIOMED-2 Concerted Action BMH4-CT98-3936. Leukemia. 2003;17(12):2257-2317. doi:10.1038/sj.leu.2403202
2. Gazzola A, Mannu C, Rossi M, et al. The evolution of clonality testing in the diagnosis and monitoring of hematological malignancies. Ther Adv Hematol. 2014;5(2):35-47. doi:10.1177/2040620713519729
3. Kokovic I, Jezersek Novakovic B, Novakovic S. Diagnostic value of immunoglobulin k light chain gene rearrangement

analysis in B-cell lymphomas. Int J Oncol. 2015;46(3):953-962. doi:10.3892/ijo.2014.2790
4. Wang J, Zhao S, Niu T, et al. Prognostic relevance of immunoglobulin heavy chain rearrangement and immunoglobulin kappa light chain rearrangement in patients with diffuse large B cell lymphoma. Oncologist. 2025;30(3):oyaf016. doi:10.1093/oncolo/oyaf016

Performance

Method Description
Genomic DNA is extracted from all specimens. In the polymerase chain reaction (PCR) assay, a total of 34 upstream and 5 downstream primers are used (Invivoscribe IGH and IGK gene clonality reagents). The primers are designed to amplify fragments from all theoretical rearrangements of the immunoglobulin heavy and kappa light chain genes. Each unique rearrangement should produce PCR fragments of unique sizes. The primers cannot amplify anything if the immunoglobulin genes are not rearranged because the distance is too great. The primers are labeled with a fluorescent tag so that the PCR product can be detected. The PCR fragments are analyzed by capillary gel electrophoresis using a genetic analyzer for fragment size and amount.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
7 to 14 days

Specimen Retention Time
Fresh/Frozen Tissue: 2 weeks; Extracted DNA: 3 months; FFPE tissue: Unused portions of blocks will be returned to the client. Unstained slides/body fluid: Not retained

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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 was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo

Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

81261-IGH (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas B-cell), gene rearrangement analysis to detect abnormal clonal populations; amplified methodology (eg. polymerase chain reaction)
81264-IGK (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell) gene rearrangement analysis, evaluation to detect abnormal clonal populations

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BCGRV	Immunoglobulin Gene Rearrange, V	61113-7

Result ID	Test Result Name	Result LOINC® Value
MP017	Specimen:	31208-2
19915	Final Diagnosis:	34574-4
608950	Signing Pathologist	19139-5