

# SO 1.92 Genetic Test Utilization and Approval

**Purpose** Children’s Minnesota Laboratory has a program for Genetic Test Utilization and Approval. Genetic test choices are rapidly changing, expensive, and turnaround time can be lengthy. Selection of the most appropriate genetic test is vital for timely diagnosis in addition to the cost and potential financial impact on patient families.

This document provides instructions for the review and approval of genetic test orders received in the Children’s Minnesota laboratories.

**Policy Statements**

- This policy describes a program for genetic test utilization management involving a rotation of Genetic Counselors (GC) from the Children’s Genetics Clinic and the referral testing laboratory staff. The Medical Director will oversee the process and assist when necessary.
- All genetic orders must be reviewed and approved by a genetic counselor from Children’s Genetics Clinic. This includes orders placed by:
  - internal providers not part of the Children’s Genetics Clinic
  - external providers with privileges at Children’s Minnesota

This also includes the following types of orders (example list, may not be exhaustive):

- Add-to orders
- Known familial mutations
- DNA based testing with 3<sup>rd</sup> party (insurance) billing
- Outpatient Whole Exome or Genome
- Note: Inpatient Whole Exome or Genome has a separate review process
- Remote Collection Orders

This does NOT include:

- Bone Marrow Testing
- Leukemia/Lymphoma Diagnostic and/or Treatment Monitoring
- BCR/ABL
- Research testing
- Pathology testing

- This process is for appropriate genetic test selection.
- Testing may be approved as is, modified, or denied. Modifications will be discussed with the ordering provider.
- This approval process is a separate process from the Prior Authorization process required by many insurance plans.
- Whole Exome Sequencing or Whole Genome Sequencing will also be reviewed by a Children’s Minnesota pathologist

**Materials**

- Email template for “test review”
- Price lists/fee schedules provided by various reference laboratories

**Procedure**

Step	Action	Related Document
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1	Clinician places order in Cerner.	
2	<p>Send out staff will provide the following information to GC on-call via email:</p> <ul style="list-style-type: none"> <li>• Patient Name (last name, first name)           <ul style="list-style-type: none"> <li>• MRN</li> <li>• Ordering provider (last name, first name)</li> <li>• Date of collection/order</li> <li>• Test name</li> <li>• Reference lab</li> <li>• Price of test (cost to Children's)</li> <li>• Type of specimen</li> <li>• Add-on request? Y/N</li> <li>• Forms required, if applicable (Send web-link if no paperwork provided)</li> </ul> </li> </ul>	
3	<p>Send-out staff will generate an email to the "GC Team"          In the subject line, type "Campus-Last name, First name Test Review Request"           Ex. "STP- Smith, Jane"</p>	
4	Genetic Counselor will review the test for appropriateness	
5	<p>The Genetic Counselor will approve, deny or modify the test order.</p> <p>If necessary, the Genetic Counselor will contact the ordering provider to recommend changing the order, canceling the order, or ordering the testing reflexively.</p>	

6	<p>Genetic Counselor will complete the review document</p> <ul style="list-style-type: none"> <li>• <b>Tests to be performed</b> <ol style="list-style-type: none"> <li>1. Approved</li> <li>2. Modified (if changed, describe)</li> <li>3. Canceled</li> <li>4. Changed to reflexive testing</li> </ol> </li> <li>• <b>Notes</b></li> </ul>	
7	<p>Once completed, the Genetic Counselor will reply back to the email from Lab Send Outs.</p>	

**Procedural Notes**

1. The Section Medical Director overseeing molecular testing or the Laboratory Medical Director are available for assistance for questions. If both are unavailable, contact the pathologist on-call.
2. The Section Medical Director overseeing molecular testing or the Laboratory Medical Director will review Inpatient Whole Exome Sequencing or Whole Genome Sequencing requests. Children's Genetics is the only department approved to order Whole Exome Sequencing or Whole Genome Sequencing tests. If both are unavailable, contact the pathologist on call.
3. Weekend reviews: Send Cytogenetic test specimens to performing lab, do not wait for review to come back. Testing will be reviewed by the genetic counselor the next business day.
4. Questions on weekends can be reviewed by the Geneticist on-call in Amion.
5. See related procedure [SO 1.90 Test Utilization Management Review Process](#)

**References**

1. Pediatric Laboratory Utilization Guidance Services (PLUGS). Seattle Children's Hospital. August 2013.
2. Paxton, Anne. *How Labs Are Taming Test Utilization*. CAP Today. June 2013.

**Approval Workflow**

Support Services Technical Specialist/Laboratory Director

**Historical Record**

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	Lisa Kappenman	09/09/2013	Initial Version

2	Lisa Kappenman	09/10/2013	Updated email template and process
2	Lisa Kappenman	09/12/2013	Updated hyperlinks
3	Jennifer Jacobsen	12/18/2017	Modified to be genetic testing specific Updated contacts
	Jennifer Jacobsen	12/23/2020	Review-No changes
4	Sandra Tekmen	11/01/2024	Omitted outdated process to save forms, process is maintained by email; omitted outdated contacts; omitted mention of genetics department review being required for orders placed by genetics department.; omitted pharmacogenomic testing from review list; added related document SO 1.90.