

Asparaginase FAQs	
Question	Answer
What are the asparaginase assays?	The L-asparaginase assays are laboratory developed tests (LDT) to determine the enzyme activity of L-asparaginase or the presence of anti-asparaginase antibodies in patients who have been treated with Oncaspar® or Erwinaze®. These assays have been validated and are performed in a CLIA certified high complexity laboratory.
What is the difference between the activity assay and the antibody assay?	<p>L-<b>asparaginase activity</b> test determines the concentration of drug which can help physicians identify patients experiencing “silent inactivation” as well as to ensure that adequate asparaginase activity is present during asparaginase treatment. The assay is performed using a serum sample obtained from the patient after treatment.</p> <p>The ELISA <b>antibody assay</b> determines the presence or absence of antibodies to Asparaginase. This test allows clinicians to monitor their patient’s antibody levels in a manner similar to therapeutic drug monitoring as done with the asparaginase activity assay. This assay reports the presence or absence of antibodies to asparaginase in the sample, but it does not distinguish between general antibodies towards asparaginase and neutralizing antibodies.</p>
How much does the test cost?	<ol style="list-style-type: none"> <li>1. Asparaginase Activity Assay is <b>\$495</b></li> <li>2. Asparaginase Panel is <b>\$495</b> (includes both activity and antibody results)</li> </ol>
What are the CPT codes?	for the <b>activity assay it is 82657x2;</b> for the <b>asparaginase panel is 82657x2 AND 83516.</b>
Do you bill insurance?	No, we do not bill insurance. We only bill the institution sending in the sample. We do not require that an institution be set up prior to receiving a sample.
How do I order supplies?	Visit our website. There you can find our Sample Submission form, Kit Order Form and Laboratory Manual
Do I need to order your kits to submit a sample?	No. You can use supplies you already have on hand, it just needs to be collected in a red-top tube or gel-barrier tube, to separate serum from red blood cells. Please only submit the serum. Each sample needs a minimum of 0.5 mL to perform both assays.

Are you CLIA certified?	Yes, we are, and we are also Joint Commission accredited. Both certificates can be found on the front page of our website, at the bottom.
What is your turnaround time?	98% of our samples are reported out within five hours of receipt. All samples are reported out the same day or within one day of receipt.
How to ship the sample	Frozen or refrigerated specimens must be transported in insulated containers surrounded by an ample amount of dry ice (frozen) or frozen cold packs (refrigerated) to keep the specimen at optimal storage condition until arrival to the laboratory. Specimens received internationally must be shipped using dry ice. It is also recommended that samples shipped during the summer months be shipped frozen on dry ice due to the potential exposure to high temperatures during shipment.
Specimen Requirements	<p><b>Specimen:</b> Serum</p> <p><b>Collection:</b> Venous Collection, red-top tube or gel-barrier tube, separate serum from RBCs within two hours, freeze/refrigerate serum immediately</p> <p><b>Volume:</b> 0.5 – 2 mL</p> <p><b>Storage Instructions:</b> Freeze prior to transport. Sample may be refrigerated at 2°C to 8°C</p>
Specimen Identification	<p>All samples and requisitions MUST be labeled with the following information.</p> <ol style="list-style-type: none"> <li>1. The Patient's first and last name or a unique ID code is required</li> <li>2. The second patient identifier may be one of the following: <ul style="list-style-type: none"> <li>• Date of birth.</li> <li>• Other unique patient identifier, e.g. medical record number, social security number.</li> <li>• Barcode labels can be used if barcode matches the unique identifiers on the printed requisition, including our provided barcode or requisition # where applicable.</li> <li>• Time and date of collection</li> </ul> </li> </ol>

How is your activity assay different from your competitor's activity assay?

Granger Genetics was the company which first validated the asparaginase activity assay in conjunction with the pharmaceutical companies which owned the two drugs tested in the assay.

- In 2016, Granger Genetics performed a major revalidation of the original assay (which is the assay performed by our competitors).
- The science of the assay is the same as our competitor's assay, but we streamlined the process and introduced some automation techniques which make the assay more robust and therefore reduced human error.
- We also moved our data processing away from an excel spreadsheet to a validated data processing software which reduced the need for human interpretation of the results allowing for another reduction in human error.