



## Blood Level Testing Patient Information

Imatinib Blood Level Testing (BLT) is a method of determining the trough level, or lowest level, of the drug in the blood. While most of the research thus far has focused on CML patients on Gleevec treatment, preliminary data suggests there may be a relationship between the trough levels of imatinib and clinical benefit in GIST. Numerous factors can affect this level, including body metabolism, dosage prescribed, and drug-drug interactions. Research has suggested that a level of 1100 ng/ml may be the therapeutic level, or optimal threshold for drug efficacy. In a recent study conducted in GIST patients, trough imatinib levels below 1100 ng/ml were associated with lower clinical benefit and significantly faster rates of progression<sup>1</sup>. Specifically, their data showed that median time to progression in patients with trough levels lower than 1100 ng/ml was 11.3 months, while those with trough levels over 1100 ng/ml had a media time to progression of more than 30 months. A great deal of research is now being devoted to further investigate the relationship between imatinib exposure and efficacy to develop guidelines for the potential of BLT use in clinical practice.<sup>2,3</sup>

In addition to suggesting clinical benefit, routine blood level testing may also provide the physician with vital information. Drug levels have been shown to change over time, so for new patients starting imatinib treatment, BLT may be useful for determining a baseline level of the drug. Regular monitoring following the initial testing may prove a beneficial tool in tracking the patient's response to the drug over time and managing side effects. Such monitoring can be a helpful tool for providing care as recent studies have shown that disease progression may be due to low imatinib levels while extremely high imatinib levels in the blood may cause severe side effects. A leading GIST specialist has estimated that at least 25% of GIST patients may be under-dosed and that they could have better responses to therapy if their blood concentration were monitored and their dose adjusted based on those results<sup>1</sup>. Blood level testing is a crucial tool in developing individualized treatment plans.

Blood Level Testing is now being offered to GIST patients through Avantix Laboratory. It is free for the patient. Novartis is funding the effort at this CLIA-certified laboratory with significant expertise in blood testing. To make this testing easily accessible to our GIST patient community, the Life Raft Group has obtained imatinib BLT test kits from Avantix Laboratory ([www.gistalliance.com](http://www.gistalliance.com)). With the help of their physician, we hope all patients will be able to utilize this crucial tool to help in their fight against GIST.

<sup>[1]</sup> Demetri GD, Wang Y, Wehrle E, Blanke C, Joensuu H, von Mehren M. Correlation of imatinib plasma levels with clinical benefit in patients (Pts) with unresectable/metastatic gastrointestinal stromal tumors (GIST) (abstract, oral presentation). 2008 Gastrointestinal Cancers Symposium. Orlando, January 25–27, 2008

<sup>[2]</sup> Widmer N, Decosterd LA, Leyvraz S, Duchosal MA, Rosselet A, et al. Relationship of imatinib-free plasma levels and target genotype with efficacy and tolerability. *British Journal of Cancer* 98:1633-1640. 2008

<sup>[3]</sup> Picard S, Titier K, Etienne G, Teilhet E, Ducint D, et al. Trough imatinib plasma levels are associated with both cytogenetic and molecular responses to standard-dose imatinib in chronic myeloid leukemia. *Blood* 109: 3496-3499

To have this test done properly, you as a patient must be sure to complete certain steps. If you have questions about this procedure, please contact Avantix Lab (1-866-990-0007).

- 1. Choosing your Physician:** Please call your physician and ask if he/she will perform this test. Since this is a relatively new procedure in the GIST world, they may want to obtain more information about it. The blood draw procedure also calls for a centrifuge (a machine used to separate the blood). Make certain the physician willing to perform the procedure has access to a centrifuge. Also, if you have a port, please find out if the office has the ability to draw blood from the port during your appointment.
- 2. Timing your Appointment:** The testing protocol requires the blood be drawn no more than two hours before the next dose. Please be sure to take this into account while making your appointment. For example, if you were to take your dose at 2:00pm every day, please be sure to schedule your appointment between 12:00pm to 2:00pm and do NOT take your next dose until the testing has been performed. In circumstances where an appointment cannot be made in that 2-hour window, the blood draw can be taken up to two hours after the scheduled time for dosage, as long as the next dose has NOT been taken, making the range for testing 12:00 – 4:00pm.

Office hours may be an issue if you take your medication during early or late hours of the day. If you cannot get an appointment in your four-hour window, you may need to change the time you take your dose to make it possible to perform the test during office hours. Please speak to your doctor first and for one week leading up to the testing, please take your dosage at the time that has been set.

For patients that split their dose, the test should typically be done at the time when the patients Gleevec drug levels are at their lowest level of the day. This will typically be before their first dose of the day. For example, a patient normally takes Gleevec at 8:00 AM and 5 PM. The test should be scheduled for as close to 8:00 AM as possible, but no later than 10:00 AM and the first dose of Gleevec should not be taken until after the test. If in doubt, ask your doctor to determine what time your drug levels will be at their lowest (trough level) and this would be the time to schedule your test.

- 3. Informing your Physician:** Many doctors may want to see the procedure and the kit prior to the appointment. It may be a good idea to drop off the entire package (kit, information sheet, registration form) before your appointment so the doctor becomes familiar with the process.
- 4. Testing Day:** No fasting or other precautions have to be taken. Having all of the prior steps completed, the testing should go smoothly. It is a relatively simple procedure. The blood is drawn, centrifuged, and the plasma that is separated from the blood is collected and sent to the testing site where various procedures determine the trough level of imatinib in your blood.
- 5. Shipping Day:** Samples should be shipped to Avantix on Friday or Saturday.
- 6. Obtaining Results:** Results will be sent back to your ordering physician in 5-7 days via internet or fax. Contact them after this time period to get your results.

**Helping the GIST Community:** The Life Raft Group is conducting a survey of GIST patients and the various factors that contribute to survival. Monitoring plasma levels of imatinib is a crucial piece of this survey. Please be sure to provide us with your results once you have received them so we can continue to help the patient community. See below more information about contributing to our research.

Please provide the Life Raft Group with the following information to contribute to our extensive patient database.

Name: \_\_\_\_\_ Date of Test: \_\_\_\_/\_\_\_\_/\_\_\_\_

*I have completed Imatinib Blood Level Testing. My imatinib concentration is \_\_\_\_\_ ng/mL.*

Send us with your results:

Life Raft Group  
40 Galesi Drive, Suite 19  
Wayne, NJ 07040

OR

Email us with your results:

liferaft@liferaftgroup.org  
Subject: BLT Results

OR

Call us with your results:

Life Raft Group  
(973) 837-9092