

LABORATORY EVALUATION FORM (LE)

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	<p>The Laboratory Evaluation (LE) form should be completed each time laboratory tests are performed.</p> <p>The Laboratory Evaluation form should be completed at the following protocol evaluations: Screen 1, Baseline, Treatment days 7, 14, and 28, Treatment weeks 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48, and Follow-up weeks 4, 12, 24, 36, and 48, or at the time of premature discontinuation during the treatment or follow-up period.</p> <p>The Laboratory Evaluation form should also be completed if laboratory tests are performed at any other time outside of protocol evaluations such as unscheduled visits, adverse events, or at the time of premature discontinuation from treatment or follow-up.</p>
PATIENT ID	<p>Record the Patient ID number on the cover page and in the top right hand corner of page 1.</p>
TIMEPOINT	<p>Record the time point of the current evaluation.</p> <p><u>Unscheduled visit:</u> Laboratory tests are performed outside of the protocol evaluations, either for an unscheduled visit evaluation, adverse event, or other reason.</p> <p><u>Premature discontinuation:</u></p> <ol style="list-style-type: none"> (1) Treatment is discontinued prior to 48 weeks other than for those determined to be non-responders at Treatment week 24. All forms required at Treatment week 48 must be completed at the time that study medication is discontinued. (2) Follow-up is discontinued during the first 24 weeks. All forms required at follow-up week 24 must be completed at the time of the discontinued follow-up.
DATE OF SAMPLE	<p>Record the date (month/day/year) that the sample was taken for the laboratory tests.</p>
MILITARY TIME	<p>Record the time that the sample was taken for the laboratory tests in military time.</p>
RESULTS	<p>Check "Yes" if the results are reported from the primary laboratory indicated. If results are reported from another laboratory other than the primary one used, check "No".</p> <p>If "No", record the upper and lower limit normal lab values on back of the form for the laboratory that was used. If the time point is the Screen 1 visit, also complete the laboratory normals for labs 14-20.</p> <p>GENERAL INSTRUCTIONS: Record the result for each test. If the test is not completed, check "Not done".</p>

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	<p>SPECIFIC INSTRUCTIONS:</p> <p><u>Pregnancy test:</u> Check “Positive” or “Negative” to indicate the results. This lab should be completed at Screen 1, Baseline, all treatment visits except Days 2, 3, and 21, and all follow-up visits.</p> <p>If the result is positive, the Principal Investigator should be notified immediately and study medications discontinued.</p> <p><u>Labs 2-6:</u> These labs should be completed at Screen 1, Baseline, all treatment visits except Day 2, 3, and 21, and all follow-up visits.</p> <p><u>Labs 7-11:</u> These labs should be completed at Screen 1, Baseline, all treatment visits except Days 2, 3, 7, and 21, and all follow-up visits.</p> <p><u>Total bilirubin exception:</u> This lab does not need to be completed during the follow-up phase.</p> <p><u>Labs 12-15:</u> These labs should be completed at Screen 1, all treatment visits except Days 2, 3, 7, and 21, and Follow-up weeks 12, 24, and 48.</p> <p><u>TSH:</u> This lab should be completed at Screen 1, Treatment weeks 12, 24, 36, and 48, and Follow-up weeks 12, 24, and 48.</p> <p><u>Prothrombin time and INR:</u> These labs should be completed at Screen 1, Treatment weeks 24 and 48, and Follow-up weeks 12, 24, and 48.</p> <p><u>Glucose:</u> This lab should be completed at Screen 1, Treatment weeks 2 to 20, and Follow-up weeks 12 and 48. Fasting glucose should be collected at Baseline, Treatment weeks 24 and 48, and Follow-up week 24.</p> <p><u>Triglycerides and Insulin (fasting):</u> These labs should be completed at Baseline, Treatment weeks 24 and 48, and Follow-up week 24.</p> <p>Fasting labs should be collected after fasting for 8 hours.</p>