New Biologics Monitoring Assays help physicians maximize treatment response using a personalized, patient-specific approach

- Help aid in titrating doses or adjusting frequency to optimize effectiveness1-3
- May help avoid lack of response due to under-treatment1
- Assist in preventing and managing loss of response due to immunogenicity4-5
- Minimize cost to patient by avoiding unhelpful dose escalation, especially in the setting of immunogenicity1,6

LabCorp Biologic Tests provide both drug concentration (TDM) & anti-drug antibody (immunogenicity)

**Therapeutic Drug Monitoring (TDM)**
- Biologics have variable pharmacokinetics.3,7
- Dosing by weight and empiric dose adjustment are inefficient and suboptimal.3,7
- TDM for Biologics is a valuable tool to evaluate doses and to tailor dose adjustments to your individual patient.3,7
- TDM can help differentiate under-treatment from other causes of lack of response.
- Proactive dose optimization using TDM may improve clinical scores and prolong duration of anti-TNF therapy.1
- TDM has been shown to be cost-effective and may direct more appropriate care.1,6

**Immunogenicity Testing (Anti-drug Antibody level)**
- All biologics have the potential to induce an antibody-mediated immune response.
- Close to half of IBD patients on biologic therapy may develop anti-drug antibodies.4,8,9
- Anti-drug antibodies may appear as early as after the first infusion and persist for years.8
- Anti-drug antibodies can adversely affect the amount of drug in the body.8
- Sufficient drug levels (e.g. infliximab >3ug/mL), concomitant use of immunomodulating agents, and regular dosing may protect against the risk of developing anti-drug antibodies.17,19
Interpreting Drug Concentrations

- Detectable drug levels are associated with better clinical outcome as measured by mucosal healing, lower C-reactive protein, higher remission rate, and less relapse.1,2,10,11
- Target ranges and maximally effective concentrations have not been established.3
- Optimal drug concentration depends on the desired therapeutic endpoint and may differ case by case.12

| Drug            | Normal half-life | Proposed Target Trough Concentrations$ | $Note: These trough levels were those used in landmark studies and do not necessarily translate into general recommendations for individual patients. *Target ranges for vedolizumab & golimumab have yet to be established.
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<tbody>
<tr>
<td>Infliximab</td>
<td>7.7 to 9.5 days</td>
<td>3 - 7 ug/mL1</td>
<td>Adalimumab Approx 2 weeks ≥ 4.9 ug/mL13</td>
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<td></td>
<td></td>
<td>5 - 10 ug/mL2</td>
<td>≥ 4.0 ug/mL for mucosal healing19</td>
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<td>≥ 10.0 ug/mL may be required for fistula healing20</td>
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<tr>
<td>Adalimumab</td>
<td>Approx 2 weeks</td>
<td>≥ 4.9 ug/mL13</td>
<td>Vedolizumab Approx 25 days &gt; 30 ug/mL has been associated with greater mucosal healing21</td>
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<tr>
<td>Golimumab</td>
<td>Approx 2 weeks</td>
<td>≥ 4.27 ug/mL correlated with greater response and remission22</td>
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References

When & where to collect blood on my patients?

- The timing of sample collection is important because the drug concentration will change during the dosing interval.
- During induction and maintenance phases, trough collections are usually recommended because target ranges are defined using TC. Blood can be drawn at any of LabCorp’s 1700 patient service centers located nationwide.

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Visit www.LabCorp.com or call 800-444-9111 for more information.