Timothy McDonald PhD FRCPath

Blood Sciences

Template A2, RD&E

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Dear Clinician

**Re: Vedolizumab Drug Level Testing at the RD&E – Service Evaluation**

For a limited time only, and the purposes of a service evaluation, we are able to offer a discounted (£15) service for measurement of Vedolizumab drug levels in IBD patient serum.

We are undertaking this service evaluation to determine if Vedolizumab drug level is correlated with disease activity score, and therefore determine if measuring Vedolizumab levels is a useful clinical tool. In addition to standard patient demographic information required for testing, we would also like to collect some clinical information as follows:

* Local IBD Genetics Reference Number
* Type of IBD
* Patient weight
* Disease activity score (HBI for Crohn’s disease or Simple colitis score for UC)
* Start date of Vedolizumab treatment course
* Last dose of Vedolizumab
* Previous αTNF medication
* Current immunomodulator therapy

Please note that a therapeutic range and interpretation of the test results is currently unavailable. We intend to publish the findings of the service evaluation once complete.

Samples can be sent via your local laboratory. We need to receive a completed service evaluation proforma (see below) along with the routine local request form. Please note, samples must be collected at trough i.e. before the next dose.

**Important:** Contact details for invoicing purposes must be provided on the form below.

If you are interested in taking part in this service evaluation, please return the attached form by email to Rachel Nice Rachel.nice@nhs.net (01392402945).

With kind regards

Dr Timothy McDonald (Consultant Clinical Scientist)

**Clinical Data Collection for Vedolizumab Drug Monitoring**

**Date of Birth** \_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_/\_\_\_\_\_

**Type of IBD ⃝** Crohn’s

⃝ UC

⃝ IBD-U

**Patient weight** \_\_\_\_\_\_\_\_\_\_Kg

**Disease activity score**

HBI *(Crohn’s only - see overleaf)* \_\_\_\_\_\_\_\_\_\_\_\_

Simple colitis score *(UC only - see overleaf)* \_\_\_\_\_\_\_\_\_\_\_\_

**Start date of Vedolizumab treatment course:** \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**Timing of sampling since start of treatment:**

⃝ week 6

⃝ week 14

⃝ annually

⃝ other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

⃝ Clinical suspicion of treatment failure Y / N

**Date of last dose of Vedolizumab:** \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**Date of blood sample collection:** \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**Confirm trough sample collection i.e. before vedolizumab dose** Y / N

**Previous αTNF medication**

⃝ Infliximab (including Remicade, Remsima and Inflectra)

⃝ Adalimumab

**Current immunomodulator therapy**

⃝ Azathioprine Dose**\_\_\_\_\_\_**mg Frequency**\_\_\_\_\_\_\_\_**

⃝ Mercaptopurine Dose**\_\_\_\_\_\_**mg Frequency**\_\_\_\_\_\_\_\_**

⃝ Methotrexate Dose**\_\_\_\_\_\_**mg Frequency**\_\_\_\_\_\_\_\_**

⃝ Prednisolone Dose**\_\_\_\_\_\_**mg Frequency**\_\_\_\_\_\_\_\_**

**Crohn’s Disease – Harvey Bradshaw Index (HBI)**

|  |  |
| --- | --- |
| **Number of liquid stools / day**  | 1 point each |
| Abdominal pain | None | **0** |
| Mild | **1** |
| Moderate | **2** |
| Severe | **3** |
| Abdominal mass | None | **0** |
| Dubious | **1** |
| Definite | **2** |
| Definite and tender | **3** |
| General wellbeing | Very well | **0** |
| Slightly below par | **1** |
| Poor | **2** |
| Very poorly | **3** |
| Terrible | **4** |
| Number of extra GI manifestations of IBD | Mouth ulcers | **1 point each** |
| Anal fissure, new fistula, perianal abscess |
| Erythema nodosum, Pyoderma gangrenosum |

**UC - Simple colitis score**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Symptom*** | ***Score*** | ***Symptom*** | ***Score*** |
| Bowel frequency (day) |  | Blood in stool |  |
| 1–3 | **0** | Trace | **1** |
| 4–6 | **1** | Occasionally frank | **2** |
| 7–9 | **2** | Usually frank | **3** |
| >9 | **3** | General well being |  |
| Bowel frequency (night) |  | Very well | **0** |
| 1–3 | **1** | Slightly below par | **1** |
| 4–6 | **2** | Poor | **2** |
| Urgency of defecation |  | Very poor | **3** |
| Hurry | **1** | Terrible | **4** |
| Immediately | **2** | Extra-colonic features | **1 point each** |
| Incontinence | **3** |  |  |