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| Test Name: | Vedolizumab drug level and free Anti-Vedolizumab Antibodies (drug-sensitive assay) |
| Referral Laboratory Name: | Blood Sciences, Royal Devon and Exeter |
| Laboratory Postage Address For Samples | Blood Sciences - Area A2  Royal Devon and Exeter NHS Foundation Trust  Barrack Road  Exeter  EX2 5DW |
| Telephone Number For Results | 01392 402935 |
| Contact Person Name, Telephone Number and Email Address | Mandy Perry, Quality Lead, Consultant Biochemist  01392 402932  mandy.perry@nhs.net |
| Laboratory Website Address | <https://www.exeterlaboratory.com/> |
| UKAS Number | 8210 |
| Is this test ISO accredited? | Yes |
| Patient Preparation: |  |
| Does the patient need to be fasting, to have stopped drugs or have any other specific requirements? | Trough (pre dose) specimen required |
| If a Blood Test: |  |
| What collection tube(s) can be used e.g. SST, EDTA, Lithium Heparin, Fluoride Oxalate or Trace Metal? | Serum |
| Is a tube containing gel acceptable? | Yes |
| Are there any other sample handling requirements e.g. protect sample from light, transport on ice? | No |
| Is centrifugation and separation required, and if so is there a time limit? | No |
| Is haemolysis or lipaemia acceptable? | Yes |
| If a Urine Test: |  |
| Random, 24hr or other collection time period? | n/a |
| Is a preservative required? (If so, what?) | n/a |
| Required pH of urine on receipt in laboratory or to be pH’d prior to storage/postage? | n/a |
| Other requirements | n/a |
| Volume/Storage/Postage: |  |
| Sample Volume - preferred and minimum | Preffered 300uL Minimum 150 µL |
| Sample Stability Info e.g. Room Temp, 4°C or -20°C | -20°C |
| Sample Storage Requirements – for our laboratory prior to posting | <7 days old, serum, may be spun or not spun |
| Posting Requirements | First class post at room temperature |
| Assay Information: |  |
| Assay Method | Enzyme linked immunosorbent assay (ELISA) Note- we use a drug sensitive anti-vedolizumab antibody ELISA assay which will only detect ‘free’ antibodies not bound to drug. Antibodies cannot be detected and will not be measured in samples with Vedolizumab drug level ≥ 3.1mg / L |
| CE Marked? | Yes |
| EQA Scheme? | Samples exchange with Immundiagnostik |
| How often is EQA performed? | Six monthly |
| Has this test had poor performance for EQA in the last year? | n/a |
| Please give details if yes to above question | n/a |
| Reference range(s) and units | Vedolizumab drug level: please see webpage <https://www.exeterlaboratory.com/test/vedolizumab-drug-levels/>  Free Anti-Vedolizumab Antibodies: ≥10 AU/mL positive |
| Measuring range(s) and Units | Vedolizumab drug level: 3.1 -200 mg/L  Free Anti-Vedolizumab Antibodies: 10 - 400 AU/mL |
| Turnaround time and/or set days of analysis | Vedolizumab drugs: 2 weeks  Vedolizumab free antibodies: 4 weeks |
| Length of sample storage by your laboratory post-analysis | 1 month |
| Cost of test | Vedolizumab drug level: £29.50  Free Anti-Vedolizumab antibody level: £80.42 |
| Analytical Sensitivity | Drug Assay: LoB 3.725 ng/mL, LoD 7.113 ng/mL, LoQ 7.113 ng/mL  ADA Assay: LoB 4.60 AU/mL, LoD 8.06 AU/mL, LoQ 10.00 AU/mL |
| Analytical Specificity | No cross-reactivity with infliximab, adalimumab or golimumab |
| Do you use NPEx for the electronic transmission of results for this test? | Yes |
| If you use NPEx please state a contact name and email address | Chris Carr – Pathology IT Manager  ccarr5@nhs.net |