

Test Name:	Adalimumab drug level and Total anti-Adalimumab Antibodies (drug tolerant 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 level recommended (immediately before next does is due)
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?	Yes - stable in whole blood and serum for 7 days at room temperature
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	Preferred: 300uL Minimum: 150 µL
Sample Stability Info e.g. Room Temp, 4°C or - 20°C	Stable in whole blood and serum for 7 days at room temperature
Sample Storage Requirements – for our laboratory prior to posting	Keep refrigerated until posting
Posting Requirements	First class post at room temperature

Assay Information:	
Assay Method	Enzyme-linked immunosorbent assay (ELISA) Note this is a drug tolerant ELISA assay which can detect anti-adalimumab antibodies in the presence of drug.
CE Marked?	Yes
EQA Scheme?	Sample Exchange with Birmingham and Sheffield
How often is EQA performed?	Quarterly
Has this test had poor performance for EQA in the last year?	No
Please give details if yes to above question	n/a
Reference range(s) and Units	Adalimumab = please see webpage: https://www.exeterlaboratory.com/test/adalimumab-drug-levels/ Anti-Adalimumab Antibodies = ≥ 6 AU/mL I would probably say ≥ 6 AU/mL = positive. Measuring range is 6-400 AU/mL
Measuring range(s) and units:	Adalimumab = 0.8 – 45 mg/L Anti-Adalimumab Antibodies = 6 – 400 AU/mL
Turnaround time and/or set days of analysis	10 working days
Length of sample storage by your laboratory post-analysis	4-6 weeks
Cost of test	£29.50 per test
Analytical Sensitivity	Drug assay: LoB 2.3 ng/mL Antibody assay: LoB 2.643 AU/mL, LoD 5.067 AU/mL, LoQ 10 AU/mL
Analytical Specificity	Drug assay: no cross reactivity to other plasma proteins infliximab or golimumab antibodies was observed. Antibody assay: no cross-reactivity observed to anti-infliximab antibodies.
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