York Foundation Trust R&D Unit
Guidance Document
R&D/G10

Analyte Reference Interval Updates

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

UNCONTROLLED DOCUMENT WHEN PRINTED

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Approved by:	Name/Position:	Lydia Harris, Head of R&D
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	Date:	9th September 2020
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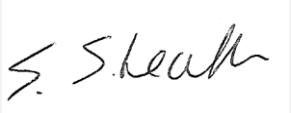
	Signature:	
	Date:	9th September 2020

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

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Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	13th January 2020	
2.0	1st June 2020	May 2020 information update added. General guidance section added. Email addressed updated to direct the user straight to the test directory. List of updates added. The document has been renamed so that it is not limited to one specific analyte reference interval update and can be used to issue guidance for subsequent updates.
3.0	1st October 2020	Specific IgE reference interval updated July 2020. Anti-SARS-CoV-2 added to the test repertoire August 2020.

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General Guidance

For the full list of up-to-date analyte reference intervals, please visit the York Teaching Hospital NHS Foundation Trust website. Information regarding specimen type, tube type, minimum volume, stability, turnaround time, clinical indications, limitations and laboratory information is also available.

https://www.yorkhospitals.nhs.uk/our-services/a-z-of-services/lab-med/test-directory/

If you have any queries regarding the content of this notification then please do not hesitate to contact the laboratory using the contact details provided below.

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Analyte Added – August 2020

On 27th August 2020 Clinical Biochemistry added Anti-SARS-CoV-2 to the test repertoire.

A summary table displaying the analyte can be found below;

Test	Sample Type	New Reference Interval Effective 27/08/20	Superseded Reference Interval
Anti-SARS-CoV-2	Serum	Interpretive result provided: Negative for anti-SARS-CoV-2 antibodies Positive for anti-SARS-CoV-2 antibodies	N/A

Analyte Reference Interval Update – July 2020

On 15th July 2020 Clinical Biochemistry updated the Specific IgE reference interval which will replace the previously used reference interval.

A summary table displaying the new reference interval can be found below;

Test	Sample Type	New Reference Interval Effective 15/08/20	Superseded Reference Interval
Specific IgE	Serum or plasma	Class Result (KUA/L) 0 <0.10 –0.35 1 0.35 – 0.70 2 0.70 – 3.50 3 3.50 – 17.5 4 17.5 – 50 5 50 – 100 6 >100	Contact Referral Laboratory

Information Update – May 2020

On 13th May 2020 Clinical Biochemistry updated test information for Collagen type 1 cross-linked C-telopeptide (CTx / Beta crosslaps), DPD mutation analysis for 5-fluorouracil (5-FU) toxicity, Cystatin C (and CKD-EPI eGFR), Infliximab (Remsima / Remicade), Apoliprotein E Genome, IgG Subclasses, Clobazam and Aspergillus Serology.

No analyte reference intervals were updated.

A summary table displaying the new test information can be found below;

Test	Update(s) Effective 13/05/20
Collagen type 1 cross-linked C-telopeptide (CTx / Beta crosslaps)	Test name changed to Collagen type 1 corss-linked C-telopeptide (CTx / Beta crosslaps). Common abbreviations updated to CTx. Special Precautions changed to Fasting sample. Must be received within 3 hours of collection. Centrifuge and freeze immediately. Stability changed to 3h at 20-25°C, > 1 year at -20°C. Reference laboratory contact telephone number changed to 01693 286929/ 01603 287945. Limitations changed to Large circadian variation. Minimise effects by collecting fasting morning sample. Notes changed to Test only available for Consultant Endocrine / Metabolic Medicine and Rheumatology requestors.
DPD mutation analysis for 5-fluorouracil (5-FU) toxicity	Added.
Cystatin C (and CKD-EPI eGFR)	Added
Infliximab (Remsima / Remicade)	Test name changed to Infliximab (Remsima / Remicade). Reference laboratory changed to Napp Pharmaceuticals Limited funds the provision of the Remsima ® testing services provided by Exeter Clinical Laboratories International. This service is only available to healthcare professionals for use with patients who have been prescribed Remsima. https://www.exeterlaboratory.com/requestor-login/. Clinical indication changed to Remsima is an anti-inflammatory medicine that contains the active substance infliximab. Infliximab is a monoclonal antibody which specifically targets and neutralises TNF-α. It is usually used in adults with immune-system disease such as Crohn's or ulcerative colitis.
Apoliprotein E Genome	Reference laboratory changed to Northern Genetics Service The Newcastle upon Tyne Hospitals NHS Foundation Trust, NE1 3BZ. Turnaround time updated to 1 calendar month. Minimum volume changed to 0.5 mL.
IgG Subclasses	Reference laboratory changed to Protein Reference Unit PO BOX 894 Sheffield S5 7YT 0114 226 9196.
Clobazam	Reference laboratory changed to Therapeutic Drug Monitoring Unit Chalfont Centre for Epilepsy, Chesham Lane, Buckinghamshire, SL9 0RJ, 01494 601 423/ 355. Turnaround time changed to 5 days. Minimum volume changed to 0.2 mL.
Aspergillus Serology	Stability changed to Total and specific IgE is analysed in York (further details - see entry for IgE) and precipitins are analysed and the Protein Reference Unit.

Analyte Reference Interval Update – December 2019

On 23rd December 2019 Clinical Biochemistry updated calcium, conjugated bilirubin, ferritin, follicle stimulating hormone (FSH), free T4, lactate dehydrogenase (LDH), microalbumin/ creatinine, oestradiol, protein/ creatinine ratio, testosterone, urine chloride, urine creatinine, urine potassium and urine sodium reference intervals which will replace the previously used reference intervals.

A summary table displaying new reference intervals the can be found below;

Test	Sample Type	New Reference Interval Effective 23/12/19	Superseded Reference Interval
Calcium	Serum	Adults: 2.2-2.6 mmol/L (Recommended by Pathology Harmonisation Reference Group) 1 month to 16 years of age: 2.2-2.7 mmol/L <1 month: 2.0-2.7 mmol/L	Adults: 2.0-2.6 mmol/L (Recommended by Pathology Harmonisation Reference Group) 1 month to 16 years of age: 2.2-2.7 mmol/L <1 month: 2.0-2.7 mmol/L
Conjugated Bilirubin	Serum	Interpretation provided on report.	<4 µmol/L (Quoted by the manufacturer)
Ferritin	Serum	Male: 30 - 400 µg/L (Quoted by the manufacturer) Females < 60 years: 30 - 150 µg/L (Quoted by the manufacturer) Females > 60 years: 30 - 260 µg/L (Derived in-house)	Male: 30 - 400 µg/L Females < 60 years: 13 - 150 µg/L Females > 60 years: 13 - 260 µg/L
Follicle Stimulating Hormone (FSH)	Serum	Females: 1 - 10 years: < or equal to 6.0 IU/L (Clinical Biochemistry 2010; 43: 1045 – 1050) Follicular: 3.5 - 12.5 IU/L Ovulation: 4.7 - 21.5 IU/L Luteal: 1.7 - 7.7 IU/L Post-menopausal: 25.8 - 134.8 IU/L (Quoted by the manufacturer) Males: 1 - 5 years: < or equal to 1.9 IU/L 6 - 10 years: < or equal to 2.3 IU/L 11 - 15 years: < and equal to 6.9 IU/L 16 - 20 years: < or equal to 9.7 IU/L (Clinical Biochemistry 2010; 43: 1045 – 1050) 1.5 - 12.4 IU/L (Quoted by the manufacturer)	Females: Follicular: 3.5 - 12.5 IU/L Ovulation: 4.7 - 21.5 IU/L Luteal: 1.7 - 7.7 IU/L Post-menopausal: 25.8 - 134.8 IU/L Males: 1.5 - 12.4 IU/L
Free T4	Serum	0 – 6 Days: 11 – 32 pmol/L 7 Days – 3 Months: 12 – 28 pmol/L 3 Months – 12 Months: 12 – 26 pmol/L 1 Year – 6 Years: 12 – 23 pmol/L 7 Years – 11 Years: 13 – 22 pmol/L 12 Years – 20 Years: 13 – 21 pmol/L Adults: 12 – 22 pmol/L 1st Trimester: 12 – 20 pmol/L 2nd Trimester: 10 – 17 pmol/L 3rd Trimester: 8 – 16 pmol/L (Quoted by the manufacturer)	0 – 6 Days: 11 – 32 pmol/L 7 Days – 3 Months: 12 – 28 pmol/L 3 Months – 12 Months: 12 – 26 pmol/L 1 Year – 6 Years: 12 – 23 pmol/L 7 Years – 11 Years: 13 – 22 pmol/L 12 Years – 20 Years: 13 – 21 pmol/L Adults: 12 – 22 pmol/L 1st Trimester: 12 – 20 pmol/L 2nd Trimester: 10 – 17 pmol/L 3rd Trimester: 8 – 15.6 pmol/L (Quoted by the manufacturer)

*The **Summary of Reference Interval Change by Test** continues on the next page.*

Test	Sample Type	New Reference Interval Effective 23/12/19	Superseded Reference Interval
Lactate Dehydrogenase (LDH)	Serum or Plasma	Neonates (4-20 days): 225-600 U/L Children (<15 years old): 120-300 IU/L Adult females: 135-214 IU/L Adult males: 135-225 IU/L	Children (2-15 years old): 120-300 IU/L Adult females: 135-214 IU/L Adult males: 135-225 IU/L - New ranges as of 03/04/18 (Quoted by the manufacturer)
Microalbumin/ Creatinine Ratio	Urine	<3.0mg/mmol	Non-diabetic: <30.0 mg/mmol creatinine Diabetic Females: <3.5mg/mmol creatinine Diabetic Males: <2.5 mg/mmol creatinine
Oestradiol	Serum	Male: < 223 pmol/L Female: Follicular phase: < 854 pmol/L Ovulation: 151 - 1461 pmol/L Luteal phase: 82 - 1251 pmol/L Post-menopausal < or equal to 505 pmol/L (Quoted by the manufacturer)	Male: 94.8 - 223 pmol/L Female: Follicular phase: 45.4 - 854 pmol/L Ovulation: 151 - 1461 pmol/L Luteal phase: 81.9 - 1251 pmol/L Post-menopausal <18.4 – 505 pmol/L (Quoted by the manufacturer)
Protein/ Creatinine Ratio	Random or 24 Hour Urine	<30mg/mmol in pregnancy. Otherwise, please refer to NICE GC 182 (CKD).	24 hour urine: 0.05 - 0.08g/ 24 hours Random urine: 0 - 50mg/mmol creatinine
Testosterone	Serum	Males: 1 - 5 years: <0.42 nmol/L 6 - 10 years: <0.82 nmol/L 11 - 15 years: <28.8 nmol/L 16 - 20 years: 3.55 - 35.08 nmol/L, (Clinical Biochemistry 2010; 43: 1045 – 1050) 20 - 49 years: 8.64 - 29.0 nmol/L > or equal to 50 years: 6.68 - 25.7 nmol/L (Quoted by the manufacturer) Female: 1 - 5 years: <0.42 nmol/L 6 - 10 years: <0.82 nmol/L 11 - 20 years: <2.72 nmol/L (Clinical Biochemistry 2010; 43: 1045 – 1050) 20 - 49 years: < or equal to 1.67 nmol/L > or equal 50 years: < or equal to 1.42 nmol/L (Quoted by the manufacturer)	Male 20 - 49 years: 8.64 - 29.0 nmol/L Male ?50 years: 6.68 - 25.7 nmol/L Female 20 - 49 years: 0.290 - 1.67 nmol/L Female ? 50 years: 0.101 - 1.42 nmol/L (Quoted by the manufacturer)
Urine Chloride	Random Urine	110 - 250 mmol/24h	170 - 250 mmol/L (Recommended by the Pathology Harmonisation Reference Group)
Urine Creatinine	Random or 24 Hour Urine	Female: 6 - 13 mmol/24 hours Male: 9 - 19 mmol/24 hours For creatinine clearance requests, age related specific ranges are issued on the report.	Female: 8 - 13 mmol/24 hours Male: 8 - 16 mmol/24 hours For creatinine clearance requests, age related specific ranges are issued on the report.
Urine Potassium	Random or 24 Hour Urine	25 - 125 mmol/24hours Reference range for random urine not available. Result should be interpreted in conjunction with serum result.	30 - 125 mmol/24hours (Recommended by the Pathology Harmonisation Reference Group) Reference range for random urine not available. Result should be interpreted in conjunction with serum result.

*The **Summary of Reference Interval Change by Test** continues on the next page.*

Test	Sample Type	New Reference Interval Effective 23/12/19	Superseded Reference Interval
Urine Sodium	Random or 24 Hour Urine	40 - 250 mmol/24hours Reference range for random urine not available. Result should be interpreted in conjunction with serum result.	20 - 250 mmol/24hours (Recommended by the Pathology Harmonisation Reference Group) Reference range for random urine not available. Result should be interpreted in conjunction with serum result.