MES and UKAS Extension to Scope of Accreditation Tables - Weston

Document Reference: LF-GEN-WGH-MES&UKASETSTables

Laboratory Medicine at University Hospitals Bristol and Weston will comply with the requirements of all relevant regulatory bodies and is committed to continually providing high quality laboratory results by ensuring all examination procedures are fit for purpose. Part of this process is ensuring that all assays are accredited to ISO 15189:2012 initially and then updated to ISO 15189:2022, which is assessed by UKAS.

As part of a renewed network managed service contract for laboratory analysers, UHBW Laboratory Medicine are undergoing a number of analyser and assay changes and updates. This means that the laboratory will initially remove old analysers and assay from current UKAS accreditation scope in order to then reapply for Extension to Scope for new analysers and assays.

The following tables provide details on the tests undergoing this process.

<u>Weston</u>

Clinical Biochemistry:

Activity	Sample type	Comments	Accreditation Status
Osmolality – Osmolar	Serum, plasma,	No Change	Not accredited. ETS in
Gap	urine		preparation.
Glucose	CSF	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Albumin	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Alkaline Phosphatase	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
ALT	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Amylase	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Bicarbonate	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas C501	preparation.

Tables - Weston

		to Beckman DxC700AU.	
		Not yet submitted.	
Bilirubin (Total)	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
CA125	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma	to Beckman DxI. Not yet	
		submitted.	
Calcium	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
Adjusted Calcium	plasma	from Roche Cobas C501	preparation.
(calculation)		to Beckman DxC700AU.	
		Not yet submitted.	
Carbamazepine	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
CEA	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma	to Beckman DxI. Not yet	
		submitted.	
Cholesterol	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
Non-HDL Cholesterol	plasma, Li-Hep	from Roche Cobas C501	preparation.
(calculation)	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Chloride	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Cortisol	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma, citrate	to Beckman Dxl. Not yet	
	plasma, fluoride	submitted.	
	plasma		
Creatine Kinase	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas C501	preparation.
Author: Patrick Simms			Edition No: 3
Approved by: Natalia Casey	F	Page 2 of 12 A	ctive Date: 27 th January 2025

Tables - Weston

		to Beckman DxC700AU.	
		Not yet submitted.	
Creatinine	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
AKI Alerts (calculation)	plasma, Li-Hep	from Roche Cobas C501	preparation.
eGFR (calculation)	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
CRP	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Digoxin	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma <i>,</i> Li-Hep	from Roche Cobas E601	preparation.
	plasma, citrate	to Beckman DxI. Not yet	
	plasma, fluoride	submitted.	
	plasma		
Direct Bilirubin	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Ferritin	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Folate	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas E601	preparation.
		to Beckman DxI. Not yet	
		submitted.	
FSH	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma	to Beckman DxI. Not yet	
		submitted.	
Free T4	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma, fluoride	to Beckman Dxl. Not yet	
	plasma	submitted.	
Free T3	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas E601	preparation.
Author: Patrick Simms			Edition No: 3
Approved by: Natalia Casey	F	Page 3 of 12 A	ctive Date: 27 th January 2025

<u> Tables - Weston</u>



	plasma, fluoride	to Beckman DxI. Not yet	
	plasma	submitted.	
Gamma	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
Glutamyltransferase	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Gentamicin	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Glucose	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma, fluoride	to Beckman DxC700AU.	
	plasma	Not yet submitted.	
HDL Cholesterol	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
HCG	Serum	ETS platform change	Not accredited. ETS in
		from Roche Cobas E601	preparation.
		to Beckman Dxl. Not yet	
		submitted.	
lgG, lgA, lgM	Serum	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Iron	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Lactate dehydrogenase	Serum, Li-Hep	ETS platform change	Not accredited. ETS in
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
LH	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
	plasma, Li-Hep	from Roche Cobas E601	preparation.

Tables - Weston

Approved by: Natalia Casey



	plasma, fluoride	to Beckman Dxl. Not yet	
	plasma	submitted.	
Lithium	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Magnesium	Serum, Li-Hep	ETS platform change	Not accredited. ETS i
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Oestradiol	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma, citrate	to Beckman DxI. Not yet	
	plasma, fluoride	submitted.	
	plasma		
Paracetamol	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Phenytoin	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Phosphate	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Potassium	Serum, Li-Hep	ETS platform change	Not accredited. ETS i
	plasma	from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Progesterone	Serum, K2EDTA	ETS platform change	Not accredited. ETS
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma, fluoride	to Beckman DxI. Not yet	
	plasma	submitted.	
Procalcitonin	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma,	to Beckman Dxl. Not yet	
		, submitted.	

Tables - Weston



Prolactin	Serum, K2EDTA plasma, Li-Hep plasma	ETS platform change from Roche Cobas E601 to Beckman DxI. Not yet submitted.	Not accredited. ETS in preparation.
PSA	Serum, K2EDTA plasma, Li-Hep plasma	ETS platform change from Roche Cobas E601 to Beckman DxI. Not yet submitted.	Not accredited. ETS in preparation.
РТН	Serum, K2EDTA plasma	ETS platform change from Roche Cobas E601 to Beckman DxI. Not yet submitted.	Not accredited. ETS in preparation.
Salicylate	Serum, K2EDTA plasma, Li-Hep plasma	ETS platform change from Roche Cobas C501 to Beckman DxC700AU. Not yet submitted.	Not accredited. ETS in preparation.
Sodium	Serum, Li-Hep plasma	ETS platform change from Roche Cobas C501 to Beckman DxC700AU. Not yet submitted.	Not accredited. ETS in preparation.
Testosterone	Serum, K2EDTA plasma, Li-Hep plasma	ETS platform change from Roche Cobas E601 to Beckman DxI. Not yet submitted.	Not accredited. ETS in preparation.
Total Protein	Serum, K2EDTA plasma, Li-Hep plasma	ETS platform change from Roche Cobas C501 to Beckman DxC700AU. Not yet submitted.	Not accredited. ETS in preparation.
Triglycerides	Serum, K2EDTA plasma, Li-Hep plasma	ETS platform change from Roche Cobas C501 to Beckman DxC700AU. Not yet submitted.	Not accredited. ETS in preparation.
Troponin I	Serum, K2EDTA plasma, Li-Hep plasma	Introduction of assay. Performed in Beckman DxI. ETS not yet submitted.	Not accredited. ETS in preparation.

Tables - Weston



TSH	Serum, K2EDTA	ETS platform change	Not accredited. ETS in
1511	plasma, Li-Hep	from Roche Cobas E601	preparation.
	plasma, fluoride		
	plasma	to Beckman Dxl. Not yet submitted.	
Urata			Not accredited. ETS i
Urate	Serum, K2EDTA	ETS platform change	
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Urea	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
	plasma, Li-Hep	from Roche Cobas C501	preparation.
	plasma	to Beckman DxC700AU.	
		Not yet submitted.	
Vancomycin	Serum, K2EDTA	ETS platform change	Not accredited. ETS i
-	plasma, citrate	from Roche Cobas C501	preparation.
	plasma, fluoride	to Beckman DxC700AU.	
	plasma	Not yet submitted.	
Vitamin B12	Serum, Li-Hep	ETS platform change	Not accredited. ETS i
	plasma	from Roche Cobas E601	preparation.
		to Beckman Dxl. Not yet	
		submitted.	
Total Vitamin D	Serum, Li-Hep	ETS platform change	Not accredited. ETS i
	plasma	from Roche Cobas E601	preparation.
		to Beckman Dxl. Not yet	
		submitted.	
Amylase	Urine	ETS platform change	Not accredited. ETS i
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Calcium	Urine	ETS platform change	Not accredited. ETS i
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Chloride	Urine	ETS platform change	Not accredited. ETS i
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	P. Characteria
		Not yet submitted.	
Potassium	Urine	ETS platform change	Not accredited. ETS i
i otassiani		from Roche Cobas C501	preparation.
hor: Patrick Simms			Edition No:
proved by: Natalia Casey	F	Page 7 of 12 A	ctive Date: 27 th January 202

Tables - Weston

		to Beckman DxC700AU.	
		Not yet submitted.	
Sodium	Urine	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Creatinine	Urine	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Microalbumin	Urine	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Phosphate	Urine	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Urea	Urine	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Urate	Urine	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	
Protein	Urine, CSF	ETS platform change	Not accredited. ETS in
		from Roche Cobas C501	preparation.
		to Beckman DxC700AU.	
		Not yet submitted.	

MES and UKAS Extension to Scope of Accreditation Tables - Weston

Document Reference: LF-GEN-WGH-MES&UKASETSTables

University Hospitals Bristol and Weston NHS Foundation Trust

Haematology and Coagulation:

Approved by: Natalia Casey

Activity	Sample type	Comments	Accreditation status
HbA1c	Whole Blood (EDTA,	ETS platform change from	Not accredited. ETS in
	Heparin, Fluoride)	Menarini Premium 9210 to	preparation.
		Sebia Capillarys 3 Tera. Not	
		yet submitted.	
Full Blood and	Whole blood	ETS platform change from	Not accredited from
Reticulocytes:	(EDTA)	Sysmex XN-9000 to	23 rd May 2023.
Includes the following		Beckman DxH900. Not yet	Extension to scope
parameters: -		submitted.	application in
WBC, RBC, HGB, HCT,			preparation for re-
MCV,			assessment.
MCH, MCHC, RDW,			
PLT,			
PDW, IPF, NEUT,			
LYMPH,			
MONO, EOS, BASO,			
NRBC,			
MPV, RET, IRF, MDW			
Erythrocyte	Whole blood	ETS platform change from	Not accredited from
Sedimentation Rate	(EDTA)	Vescube to Alifax Test and	6 th March 2023.
		Roller 20. Not yet	Extension to scope
		submitted.	application in
			preparation for re-
			assessment.
Blood Films -	Whole blood	ETS platform change from	Not accredited from
morphology of the red	(EDTA)	Sysmex sp-10 to Beckman	23 rd May 2023.
cells, platelets and		SMS. Not yet submitted.	Extension to scope
white cells. Manual			application in
differential of white			preparation for re-
cells			assessment.
Detection of malarial	Whole blood	No change	Not accredited. ETS in
parasites: Plasmodium	(EDTA)		preparation.
falciparum,			
Plasmodium malariae,			
Plasmodium ovale &			
Author: Patrick Simms			Edition No: 3

Page **9** of **12**

Tables - Weston

Document Reference: LF-GEN-WGH-MES&UKASETSTables



Plasmodium vivax &			
Plasmodium knowlesi			
Malarial Parasite	Whole blood	No change	Not accredited. ETS in
Antigen for pLDH	(EDTA)		preparation.
(plasmodium Lactate			
Dehydrogenase).			
Detects Plasmodium			
+/- Falciparum			
Detection of	Plasma (EDTA)	No change	Not accredited. ETS in
heterophile antibodies			preparation.
in Infectious			
Mononucleosis			
Haemoglobinopathy	Whole blood	ETS platform change from	Not accredited. ETS in
screen to confirm or	(EDTA)	Arkray to Sebia Capillarys	preparation.
exclude presence of		3 Tera. Not yet submitted.	
haemoglobin variant			
and / or thalassaemia:			
Haemoglobin S			
Ante natal Sickle Cell	Whole blood	ETS platform change from	Not accredited. ETS in
and Thalassaemia	(EDTA)	Arkray to Sebia Capillarys	preparation.
Screening		3 Tera. Not yet submitted.	
Coagulation Screen: D-	Citrated blood	ETS platform change from	Not accredited from
Dimer, APTT,		Sysmex Cs-2100 to ACL	23 rd May 2023.
Fibrinogen, INR/ PT		Top 350. Not yet	Extension to scope
		submitted.	application in
			preparation for re-
			assessment.

Transfusion:

Activity	Sample type	Comments	Accreditation Status
ABO and Rh D and	Whole blood	No change	Not accredited.
DAT Grouping	(EDTA)		Voluntary suspension
			of accreditation to be
			able to submit ETS to
			8227 UKAS number.
Antibody screening	Whole blood	No change	Not accredited.
and identification	(EDTA)		Voluntary suspension
of: Anti-D, C, E, c, e,			of accreditation to be

Tables - Weston



Cw, K, k, Kp(a), Kp(b), Fy(a), Fy(b), Jk(a), Jk(b), Le(a), Le(b), P1, M, N, S, s, Lu(a), Lu(b), V, JS(a), JS(b), Xg(a).			able to submit ETS to 8227 UKAS number.
Phenotyping: Rh subgroups and Kell by Gel card (C, E, c, e, Kell) Lorne antisera with Diamed technique (Gel card) (S, s, M, Fy(a), Fy(b), JK(a), JK(b)	Whole blood (EDTA)	No change	Not accredited. Voluntary suspension of accreditation to be able to submit ETS to 8227 UKAS number.
DAT / DAGT (gel card) (IgG, C3d)	Whole blood (EDTA)	No change	Not accredited. Voluntary suspension of accreditation to be able to submit ETS to 8227 UKAS number.
Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma No change antibody.	Whole blood (EDTA)	No change	Not accredited. Voluntary suspension of accreditation to be able to submit ETS to 8227 UKAS number.
Electronic issue (using Echo analyser)	Whole blood (EDTA)	No change	Electronic Issue accredited to ISO 15189:2012 on UKAS schedule number 8227.

Document Reference: LF-GEN-WGH-MES&UKASETSTables

Essential Services Laboratory:

Activity	Sample type	Comments	Accreditation Status
C. difficile glutamate	Faeces	No change	Awaiting confirmation
dehydrogenase			of accreditation to ISO
(GDH) and toxins A &			15189:2022, post
B by Cepheid			recommendation at
			assessment on
			22/01/2025.
C. difficile glutamate	Faeces	No change	Awaiting confirmation
dehydrogenase			of accreditation to ISO
(GDH) and toxins A &			15189:2022, post
B by Techlab C. diff			recommendation at
Quik Chek			assessment on
			22/01/2025.
Detection of	Faeces	No change	Awaiting confirmation
Norovirus by			of accreditation to ISO
Cepheid			15189:2022, post
			recommendation at
			assessment on
			22/01/2025.
Detection of Flu A, B	Viral swab	No change to assay.	Awaiting confirmation
and RSV			of accreditation to ISO
			15189:2022, post
			recommendation at
			assessment on
			22/01/2025.
Detection of SARS-	Viral swab	No change to assay.	Awaiting confirmation
COV-2			of accreditation to ISO
			15189:2022, post
			recommendation at
			assessment on
			22/01/2025.