acculabs
DIAGNOSTICS

Laboratory User Guide
2026

Advanced Diagnostics for a Healthier Tomorrow

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Putting care into healthcare

Our highly skilled team fosters collaborative thinking and agile development while consistently delivering high standards of healthcare.

We are Market Led. IT Driven.

At Acculabs, proficiency and effciency are key drivers of future growth. We are committed to delivering a high-volume, low-cost service through effective automation and advanced diagnostic platforms- supporting patient care on a national scale.

As a constantly evolving organisation, innovation is central to our strategic continuity. This enables us to provide a service that is not only reliable and reputable but also responsive to the needs of our clients.

Our ethos is built on partnership. We believe that by supporting the growth of our clients, we ultimately enhance outcomes for the patients they serve.

acculabs DIAGNOSTICS

About

Established 15 years ago, Acculabs Diagnostics UK Ltd is a UKAS accredited medical laboratory No: 4680, offering a specialised service in Sexual Health Screening and Wellbeing, utilising the support services of Molecular Diagnostics, Microbiology, Andrology, Biochemistry, Serology, and Haematology. The company are experts in at-home kit assembly and can guarantee our clients the best service possible, to meet their needs.

We have proven expertise to effectively manage laboratory services, and by working with our clients we successfully develop bespoke services to suit client needs. Acculabs help the client to continue to improve their services to clinical users.

As part of our commitment to provide a pathology service of excellence and quality, this guide is designed to enable you to access and use our services.

Acculabs cover all aspects of the management of the laboratory and logistics service, allowing our clients to devote more time to other business developments:

- Courier services for collection of samples to ensure swift delivery to the laboratory for processing
- Rapid turnaround times as little as 48 hours, tailored to suit your business needs
- Consultant advice on result queries and presence in MDT meetings
- Creation and provision of testing kits (including client-specific)
- Provision of clinic supplies
- IT systems for onboarding new clients to our very own **AccuPath** LIMs (via API, SFTP)

Contact Us

Senior Management Team

Christopher Gordon	chris.gordon@acculabsdiagnostics.co.uk	CEO
Nick Gordon	nick.gordon@acculabsdiagnostics.co.uk	DCEO - Logistics
Debbie Banks	debbie.banks@acculabsdiagnostics.co.uk	DCEO - Laboratory
Jayne Harwood	jayne.harwood@acculabsdiagnostics.co.uk	Operations Manager
Graeme Buckle	graeme.buckle@acculabsdiagnostics.co.uk	Business Development Consultant
Keith Matthews	keith.matthews@acculabsdiagnostics.co.uk	Manager of Software and IT Operations

Feedback

We aim to provide a high quality of service to our clients and end-users. To do this, we want to hear from you when we do well and when we do not meet your expectations.

Acculabs has established continual improvement as a business philosophy for all processes and services to support safe and effective patient care. We continually monitor our activity and annually review this policy for its suitability and effectiveness.

We complete Management Reviews every quarter of the year, to ensure objectives are monitored locally and changes or new systems, processes or procedures are implemented effectively.

The satisfaction of service users is a key indicator of success in improvement of services. We are proactive in managing our business risks and have plans in place to
ensure service continuity under any circumstances.

We welcome feedback from our customers, stakeholders and end users.

We aim to acknowledge any complaint within 5 working days and fully resolve any issues within 30 days. If you have any suggestions as to how we can improve or to compliment us, email enquiries@acculabsdiagnostics.co.uk

Click to complete our Customer Satisfaction Survey
Or scan the QR code below:

Laboratory Opening Times
Monday to Saturday: 8am - 6pm

Logistics Opening Times

Monday to Friday: 8am - 5pm
Saturday: 8am - 3pm

Quality Assurance & Commitment

Acculabs Diagnostics UK Ltd are a UKAS accredited medical laboratory No. 4680.

We are accredited to **ISO 15189: 2022** Medical Laboratories, **ISO 9001: 2015** Quality Management Systems, **ISO 14001; 2015** Environmental Management Systems, **ISO 27001: 2022** Information Security Management Systems and **ISO 22301: 2019** Business Continuity Management Systems. We are registered with the Care Quality Commission (CQC), as an independent healthcare provider, operating under the provision of diagnostic and screening services.

Acculabs aspire to the highest standards of excellence and professionalism in the provision of high-quality laboratory services, which are safe, effective and focused on an excellent service experience. We aim to provide a high quality of service to our clients The schedule of accreditation is subject to ongoing change and our accreditation schedule can be accessed via the UKAS website (www.ukas.com). Use our **UKAS No. 4680** to search.

Acculabs strive to maintain top Quality Assurance (QA) and are assigned to many QA Programmes to support in-house quality control and excellence.

UK **NEQAS, WEQAS** and **IMMQAS** help to ensure laboratory test results are accurate, reliable and comparable. Our in-house services for Serology, Haematology, Molecular, Biochemistry, Immunology and Microbiology partake in QA Programmes.

UKAS MEDICAL 4680
Accredited to ISO 15189:2022

REGISTERED

Care Quality Commission Registered

ico.

Contact Our Quality Team

debbie.banks@acculabsdiagnostics.co.uk

jayne.harwood@acculabsdiagnostics.co.uk

Data Protection & Confidentiality

Information Acculabs may collect:

• Patient Demographics; Name, date of birth, gender, address, e-mail address, phone number, clinical information, ethnic origin, sexual orientation.

• Details of the requesting clinician, such as clinic address and contact information

• Information necessary to process invoices, including patient demographics, financial/bank/credit card information, medical and insurer specific information

How Acculabs attain personal information and why we have it:

Most personal information we process is provided to us by your clinic/healthcare provider for one of the following reasons:

- To enable the laboratory to process tests for diagnostic and screening purposes.
- To enable the laboratory to issue invoices to the requesting clinic/healthcare provider
- To enable the laboratory to report statistical data to UKHSE

Your clinician may also request your test results are sent directly to your mobile telephone number.

All data processing is under the General Data Protection Regulation (GDPR).

The lawful bases we rely on for processing this information are:

(a) We have a contractual obligation

(b) We have a legal obligation

We are legally obligated to share data with UKHSE at regular intervals, as this is required for studies conducted by this authority. We may also be obligated to share your data if requested by law enforcement or other authority.

How we store your personal information

We keep minimum data required to process your tests. We are then obligated to retain this data for the appropriate length of time defined by the Royal College of Pathologists Retention and Storage of Pathological Records and Specimens (5th Edn, 2015).

All data we store is held remotely on secure servers by our accredited **ISO 27001** IT Service Provider (Razorblue - www.razorblue.com).

Advisory Services

Acculabs are a bespoke advisory service, allowing you to experience a top-level service you can trust.

We work alongside reputable Healthcare Professionals and Clinical Consultants in Clinical Biochemistry, Immunoassay, Microbiology, Virology and Andrology.

Our Clinical Consultants work closely with our team of Biomedical Scientists to ensure testing platforms and analytics maintain current UKAS standards. Through the use of Internal Quality Control (IQC), External Quality Assurance (EQA), Haemolysis/Icterus/Lipemia (HIL) Indices, and Uncertainty of Measurement (UoM), this is achieved.

Clinical Consultants are also available to support you and your business, offering result interpretation and advice, whenever required.

Haemolysis Index

The measurement of HIL indices is important to assess the levels of haemolysis, icterus, and lipemia in a blood sample. This helps determine if any of these conditions are present in the sample at levels that could potentially interfere with the accuracy of laboratory assays.

- Haemolysis (H): Red blood cell rupture.
- Icterus (I): Excess bilirubin in the blood, often due to liver issues.
- Lipemia (L): Excess fat in the blood, often due to high triglyceride levels.

The HIL index provides a numeric value for the severity of each condition in the blood sample, helping lab technicians identify whether interference is likely, and which tests might be impacted. If the levels are too high, the sample might need to be reprocessed or recollected.

Uncertainty of Measurement

This refers to the doubt or variability in the result of a measurement. It reflects the range within which the true value of the quantity being measured is expected to lie. Every measurement has some level of uncertainty due to various factors, including:

1. Instrument limitations: No instrument is perfectly precise.

2. Environmental factors: Temperature, humidity, and air pressure can affect measurements.

3. Human error: Inconsistent reading, or errors in the technique of taking the measurement.

4. Precision of the method: The process of measurement itself may introduce errors due to limitations in the method or the procedure followed.

Maintaining the Uncertainty of Measurement is a UKAS requirement and we are responsible for ensuring our test results are reliable.
Considering the variables that may affect inaccuracy and with the support of our Clinical Consultant, we routinely evaluate this uncertainty and have routinely practiced procedures in place to manage this effectively, so clients can trust our processes.

Informed Consent

Consent to testing is the voluntary and informed permission of an individual prior to producing a sample for examination.

Consent can be given either verbally, non-verbally or in writing.

If a sample(s) is received from a patient with a request (either physically or digitally) for examinations to be performed, this will be taken as informed consent for the test(s) to be performed and examination results to be released.

Information to provide informed consent on testing can be found below.
Further information can be obtained through contacting the service provider who is offering the test(s) or through contacting the laboratory directly.

Specimen Transportation & Courier Services

Samples should be sent to the laboratory using the first-class prepaid envelope supplied or via the courier arranged as part of your contract.

All specimens must be collected in the sample tubes and placed into the leak-proof containers as supplied by the laboratory (if applicable). Lids must be firmly affixed to prevent leakage. The specimen must be placed in the specimen transport plastic bag and the request form placed in the outer sleeve. Acculabs adhere to the UN3373 Postal Requirements, to ensure Health & Safety of the environment and people.

Specimens transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations. Specimen transport bags and request forms, which are supplied to the clinics, have an absorbent pad which will immobilise the entire leakage of a liquid specimen. These used in combination with our courier service will ensure compliance with the regulations.

Acculabs Diagnostics offer a courier service to collects and delivers patient samples from clients. We adhere to ISO 140001 Environmental requirements, to ensure carbon emissions are reduced. Contact **sales@acculabsdiagnostics.co.uk** to discuss your requirements.

UN3373 refers to a code used to identify biological substances that are transported for diagnostic or clinical purposes. Specifically, it is the UN (United Nations) number for "Biological substance, Category B".

Registered Address: Unit 11-14 Wynyard Business Park, Wynyard, Billingham, TS22 5TB. Reg. Number: 07179157

Sample Types

Serum - Cat No. 367837 / KFK168. Draw Vol. 6ml.

Whole Blood Unspun - Serum Gel - Cat. No. 367954 / KFK114 Draw Vol. 5ml. Requested for Biochemistry tests, including Immunoassay and Microbiology.

Sodium Citrate or **ESR** - Cat. No. 363095 / KFK168. Draw Vol. 2.7ml. Requested for Coagulation Screens. The blue top sodium citrate is 10% citrate and 90% blood, whereas the black top sodium citrate is 20% citrate and 80% blood.

Plasma Gel - Cat. No. 367373 / KFK130. Draw Vol. 5ml. Requested for Biochemistry and Immunoassay.

EDTA - Cat. No. 367839 / KFK171. Draw Vol. 4ml. Requested for Haematology and Microbiology.

Fluoride Oxalate - Cat. No. 368921 / KFK409. Draw Vol. 4ml. Requested for Glucose, Ethanol, Lactate.

How to Invert a Blood Sample

Inverting a blood sample refers to the process of gently mixing the sample, usually in a blood collection tube, to ensure the contents are well-mixed. This is often done to prevent clotting or to ensure even distribution of additives like anticoagulants, depending on the type of test being conducted.

Here's a step-by-step process for inverting a blood sample:

1. Gather the supplies:

Blood sample in a collection tube (with or without additives like an anticoagulant).
A clean, flat surface to work on.

2. Hold the tube properly:

Hold the tube by the cap or the top, ensuring you don't touch the blood inside.
Ensure the tube is securely sealed to prevent spillage.

3. Gently invert the tube:

Turn the tube upside down and then return it to the upright position.
Repeat the inversion to properly mix using the guide provided. Do not shake the tube as shaking may cause haemolysis (destruction of red blood cells), which could interfere with the test results.

Check the sample:

Ensure the blood is evenly mixed with any additives, and there are no clumps or air bubbles.

This process is crucial to ensure the blood sample is properly prepared for the laboratory analysis, as improper mixing may affect the test results.

The image demonstrates one inversion. A gentle mix down, then up, is **one** count.

Sample Criteria

Analyte	Sample Type	Sample Stability 20°C- 25°C	Sample Stability 2°C- 8°C	Sample Stability -20°C- 5°C	UKAS Accredited Test Y/N
ALB	WBUS/ SERUM	14 Days	5 Months	4 Months	Y
ALP	WBUS/ SERUM	7 Days	7 Days	2 Months	Y
ALT	WBUS/ SERUM	3 Days	7 Days	>7 Days	Y
APOLIPOPROTEIN (A1)	WBUS/ SERUM	3 Days	8 Days	2 Months	Y
APOLIPOPROTEIN (B)	WBUS/ SERUM	3 Days	8 Days	2 Months	Y
AST	WBUS/ SERUM	4 Days	7 Days	3 Months	Y
ACTIVE B12	WBUS/ SERUM	5 Days	14 Days	6 Months	Y
BILIRUBIN TOTAL	WBUS/ SERUM	3 Days	7 Days	6 Months	Y
CALCIUM (venous only)	WBUS/ SERUM	7 Days	3 Weeks	8 Months	Y
C REACTIVE PROTEIN	WBUS/ SERUM	2 Weeks	3 Weeks	12 Months	Y
C REACTIVE PROTEIN (high sensitivity)	WBUS/ SERUM	7 Days	2 Months	3 Years	Y
CHOLESTEROL	WBUS/ SERUM	7 Days	7 Days	3 Months	Y
CORTISOL	WBUS/ SERUM	2 Days	14 Days	12 Months	Y
CREATININE	WBUS/ SERUM	7 Days	7 Days	3 Months	Y
CREATININE KINASE	WBUS/ SERUM	3 Days	7 Days	4 Months	Y
DHEAS	WBUS/ SERUM	5 Days	14 Days	12 Months	Y

Sample Criteria

Analyte	Sample Type	Sample Stability 20°C- 25°C	Sample Stability 2°C- 8°C	Sample Stability -20°C- 5°C	UKAS Accredited Test Y/N
FERRITIN	WBUS/ SERUM	3 Days	7 Days	12 Months	Y
FOLATE	WBUS/ SERUM	3 Days	3 Days	28 Days	Y
FSH	WBUS/ SERUM	5 Days	14 Days	6 Months	Y
FT3	WBUS/ SERUM	5 Days	7 Days	30 Days	Y
FT4	WBUS/ SERUM	5 Days	7 Days	30 Days	Y
GAMMA GT	WBUS/ SERUM	7 Days	7 Days	1 Year	Y
GLUCOSE	WBUS/ SERUM	8 Hours	72 Hours	N/A	Y
GLUCOSE	Fluoride oxalate plasma	3 Days	N/A	N/A	Y
Haemoglobin A1c	EDTA	3 Days	7 days	6 Months	Y
HCG	WBUS/ SERUM	5 Days	14 Days	12 Months	Y
IRON	WBUS/ SERUM	7 Days	3 Weeks	>7 Years	Y
LDL	WBUS/ SERUM	7 Days	7 Days	12 Months	Y
LH	WBUS/ SERUM	5 Days	14 Days	6 Months	Y
HDL	WBUS/ SERUM	3 Days	7 Days	12 Months	Y
MAGNESIUM	WBUS/ SERUM	7 Days	7 Days	12 Months	Y
NT-ProBNP	WBUS/ SERUM	3 Days	6 Days	24 Months	N

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Sample Criteria

Analyte	Sample Type	Sample Stability 20°C- 25°C	Sample Stability 2°C- 8°C	Sample Stability -20°C- 5°C	UKAS Accredited Test Y/N
OESTRADIOL	WBUS/ SERUM	3 Days	2 Days	6 Months	Y
PHOSPHATE	WBUS/ SERUM	2 Days	4 Days	1 Year	Y
POTASSIUM	WBUS/ SERUM	4 Hours	5 Days	Stable	Y
POTASSIUM	WBS (shortly after draw)	24 Hours	5 Days	Stable	Y
PROGESTERONE	WBUS/ SERUM	3 Days	5 Days	6 Months	Y
PROLACTIN	WBUS/ SERUM	5 Days	14 Days	6 Months	Y
PSA	WBUS/ SERUM	3 Days	5 Days	24 Weeks	Y
SHBG	WBUS/ SERUM	5 Days	7 Days	12 Months	Y
SODIUM	WBUS/ SERUM	14 Days	14 Days	Stable	Y
TESTOSTERONE	WBUS/ SERUM	5 Days	14 Days	6 Months	Y
TOTAL PROTEIN	WBUS/ SERUM	6 Days	4 Weeks	12 Months	Y
TRANSFERRIN	WBUS/ SERUM	3 Days	7 Days	4 Weeks	N
TRIGLYCERIDE	WBUS/ SERUM	3 Days	10 Days	3 Months	Y
TSH	WBUS/ SERUM	7 Days	14 Days	24 Months	Y
UIBC	WBUS/ SERUM	4 Days	7 Days	N/A	Y
UREA	WBUS/ SERUM	3 Days	7 Days	12 Months	Y
URIC ACID	WBUS/ SERUM	7 Days	7 Days	6 Months	Y

Sample Criteria

Analyte	Sample Type	Sample Stability 20°C- 25°C	Sample Stability 2°C- 8°C	Sample Stability -20°C- 5°C	UKAS Accredited Test Y/N
VITAMIN D	WBUS/ SERUM	3 Days	4 Days	24 Weeks	Y
URINE PROTEIN	URINE	1 Day	6 Days	6 Months	N
URINE CREATININE	URINE	2 Days	7 Days	6 Months	N
HIV	WBUS/ SERUM	7 Days	4 Weeks	3 Months	Y
HIV CONFIRMATION	WBUS/ SERUM	7 Days	4 Weeks	3 Months	Y
HIV PCR	EDTA	24 Hours	3 Days	N/A	Referal
SYPHILIS	WBUS/ SERUM	7 Days	14 Days	12 Months	Y
SYPHILIS CONFIRMATION	WBUS/ SERUM	7 Days	14 Days	12 Months	Y
HEP A	WBUS/ SERUM	6 Days	14 Days	3 Months	Y
HEP B CORE Ab	WBUS/ SERUM	7 Days	14 Days	3 Months	Y
HEP B SURFACE Ag	WBUS/ SERUM	7 Days	14 Days	3 Months	Y
HEP C Ab	WBUS/ SERUM	7 Days	14 Days	3 Months	Y
FBC	EDTA	30 Hours	30 Hours	N/A	N
CT	Cobas Swab/ Urine	12 Months	12 Months	12 Months	Y
Ng	Cobas Swab/ Urine	12 Months	12 Months	N/A	Y

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Sample Criteria

Analyte	Sample Type	Sample Stability 20°C- 25°C	Sample Stability 2°C- 8°C	Sample Stability -20°C- 5°C	UKAS Accredited Test Y/N
TV	Cobas Swab/ Urine	12 Months	12 Months	12 Months	N
MG	Cobas Swab/ Urine	12 Months	12 Months	12 Months	N
HSV 1 & 2	Copan M Swab	4 Days	14 Days	3 Months	Y
MRSA	Charcoal Swab	24 Hours	48 Hours	N/A	N
Genital pathogen full culture	Charcoal Swab	4 Hours	48 Hours	N/A	N
Urinary tract infection culture & antimicrobial	Plain Urine or Boric Acid	48 Hours	48 Hours	24 Weeks	N
Mycology	Nail clippings/ Skin Scrape	48 Hours	N/A	N/A	N
NG culture and antimicrobial susceptability	VCAT Plate or Charcoal Swab	24 Hours	48 Hours	N/A	N
Syphilis Multiplex	Remel Swab	72 Hours	72 Hours	N/A	Refferal

Blood taken from finger prick/ intravenous blood.

Blood draw order - Sodium Citrate, WBUS/ Serum, EDTA, Fluoride Oxalate

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Test Index

HIV

Electrochemiluminescence immunoassay for the in-vitro qualitative determination of HIV 1 p24
antigen and antibodies to HIV 1 (including group O) and HIV 2 using Roche Elecsys HIV Combi
PT reagent.

Limitations: Testing of endogenous substances and pharmaceutical compounds on assay performance was conducted by Roche and demonstrated no impact of examination results for the defined concentrations.

HIV Confirmation

HIV Confirmation consists of 2 assays:

1. Sterilab Multisure HIV: Qualitative immunochromatographic test for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2.

Limitations: False negative results may occur in individuals infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART). A negative or indeterminate result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to a recent exposure may take several months to reach detectable levels. It is recommended that testing be repeated on a specimen freshly drawn after 2-4 weeks. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, however, a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. It is recommended that testing be repeated on a specimen freshly drawn after 2-4 weeks

2. Genscreen ULTRA HIV Ag-Ab Confirmatory Assay: Qualitative enzyme immunoassay for the
detection of HIV p24 antigen and antibodies to HIV-1 (including group M and O) and HIV-2.

Limitations: Very low titres of HIV antigen or antibodies may not be detected during the first stage of the infection; consequently, a negative result indicates that the tested sample does not contain detectable HIV antigen or anti-HIV antibodies with Genscreen™ ULTRA HIV Ag-Ab. However, such a result does not preclude the possibility of exposure to an HIV-1/HIV-2 infection. The variability of HIV-1 (group M and group O) and HIV-2 allows the possibility of false negative reactions.

Syphilis

Electrochemiluminescence immunoassay for the in-vitro qualitative determination of total antibodies to Treponema pallidum, intended as an aid in the diagnosis of syphilis infection.

Limitations: Testing of endogenous substances and pharmaceutical compounds on assay performance was conducted by Roche and demonstrated no impact of examination results for the defined concentrations.

Test Index

Syphilis Confirmation

Syphilis Confirmation consists of 4 assays:

1. CAPTIATM Syphilis TA EIA Confirmatory Assay:
Immunoassay analysis uses an antigen sandwich for the detection of T.pallidum specific IgG, IgM, and IgA, enabling the test to detect antibodies during all stages of infection.
2. newbio TPHA:
Passive particle agglutination assay for the qualitative and semi-quantitative
detection of IgG and IgM antibodies to Treponema pallidum.
3. newbio RPR:
Cardiolipin antigen coated carbon particles for the detection of regain antibodies.
4. recomWell Treponema IgG/IgM Assay:
Indirect sandwich ELISA for the qualitative or
quantitative in-vitro detection of IgG/IgM antibodies against Treponema pallidum.

Limitations: Pinta, yaws, bejel and other treponemal diseases may produce reactive results with non-treponemal tests in the newbio RPR test. No interfering substances have been identified however THPA can cross contaminate with other treponemal infections such as T.pertenue and T.carateum.

Hepatitis A

Electrochemiluminescence immunoassay for the in-vitro quantitative determination of total antibodies to the hepatitis A virus.

Limitations: Testing of endogenous substances and pharmaceutical compounds on assay performance was conducted by Roche and demonstrated no impact of examination results for the defined concentrations. Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

Hepatitis B Core Ab

Electrochemiluminescence immunoassay for the in-vitro qualitative determination of IgG and IgM antibodies to the hepatitis B core antigen.

Limitations: Testing of endogenous substances and pharmaceutical compounds on assay performance was conducted by Roche and demonstrated no impact of examination results for the defined concentrations.

Hepatitis B Surface Ab
Electrochemiluminescence immunoassay for the in-vitro quantitative determination of human antibodies to the hepatitis B surface antigen.

Limitations: Testing of endogenous substances and pharmaceutical compounds on assay performance was conducted by Roche and demonstrated no impact of examination results for the defined concentrations.

Test Index

Hepatitis B Surface Ag

Electrochemiluminescence immunoassay for the in vitro qualitative determination of hepatitis B surface antigen

Limitations: Testing of endogenous substances and pharmaceutical compounds on assay performance was conducted by Roche and demonstrated no impact of examination results for the defined concentrations. According to the present state of knowledge, it can be assumed that
available assays for the detection of HBsAg cannot identify all infected blood samples or persons. A negative test result does not exclude with certainty a possible exposure to or an infection with the hepatitis B virus. Negative test results obtained for persons with a past exposure may be caused by an antigen concentration below the detection limit of this assay or the lack of reactivity of the antigens to the antibodies used in this assay.

Hepatitis C Ab

Electrochemiluminescence immunoassay for the in-vitro quantitative detection of antibodies to
hepatitis C virus

Limitations: Testing of endogenous substances and pharmaceutical compounds on assay performance was conducted by Roche and demonstrated no impact of examination results for the defined concentrations. Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration. Due to a long time period from infection to seroconversion, negative anti HCV test results may occur during early infection. If acute hepatitis C infection is suspected, measuring of HCV RNA by reverse transcriptase polymerase chain reaction (RT PCR e.g. by COBAS AMPLICOR) may give evidence of HCV infection. The detection of anti HCV antibodies indicates a present or past infection with hepatitis C virus, but does not differentiate between acute, chronic or resolved infection. It is recognized within the scientific community that presently available methods for anti HCV detection are not sensitive enough to detect all potentially infectious units of blood or possible cases of HCV infection. The antibody concentration may be beneath the detection limit of this assay or the patients´ antibodies do not react with the antigens used in this test. In addition, non-specific results cannot be ruled out with the Elecsys Anti HCV II assay.

Full Blood Count including Differential

The Sysmex XN-550 is a quantitative, multi-parameter, automated hematology analyzer for in-vitro diagnosis for the identification and enumeration of the following parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, LY%, LY#, MO%, MO#, NE%, NE#, EO%, EO#, BA%, BA#,

Limitations: Clotted samples cannot be processed. If venepuncture is di cult, or if the blood is not mixed rapidly with the anticoagulant, microclots may occur resulting in falsely elevated low platelet count. The age of the sample and incorrect storage conditions can affect results.

Test Index

Neisseria gonorrhoeae (GC) culture and antimicrobial susceptibility using GC selective agar (VCAT) in CO2 conditions.

Limitations: Failure to obtain a correctly taken sample or correctly store and transport the sample to the laboratory may give sub-optimal results possibly requiring further repeat samples to be submitted. A negative culture result cannot exclude the presence of pathogens, if symptoms persist a further sample should be submitted

Meticillin-Resistant Staphylococcus aureus (MRSA) Culture and antimicrobial susceptibility using Mueller Hinton Agar (MHA) in aerobic conditions.

Limitations: Failure to obtain a correctly taken sample or correctly store and transport the sample to the laboratory may give sub-optimal results possibly requiring further repeat samples to be submitted. A negative culture result cannot exclude the presence of pathogens, if symptoms persist a further sample should be submitted.

Genital Pathogen full culture and antimicrobial susceptibility including GC, Candida, BV,
TV.

Limitations: Failure to obtain a correctly taken sample or correctly store and transport the sample to the laboratory may give sub-optimal results possibly requiring further repeat samples to be submitted. A negative culture result cannot exclude the presence of pathogens, if symptoms persist a further sample should be submitted in up to 5 working days. This may be required to be extended if yeast identification and susceptibility testing is required as this is referred to a Mycology Reference Laboratory.

Urinary tract infection culture and antimicrobial susceptibility.

Limitations: Failure to obtain a correctly taken sample or correctly store and transport the sample to the laboratory may give sub-optimal results possibly requiring further repeat samples to be submitted. Contaminating bacteria from the external genitalia may give rise to misleading results. A negative culture result cannot exclude the presence of pathogens, if symptoms persist a further sample should be submitted.

Mycology.

Limitations: Failure to obtain a correctly taken sample or correctly store and transport the sample to the laboratory may give sub-optimal results possibly requiring further repeat samples to be submitted.

Turn-Around Time: 2-3 weeks following receipt of sample.

Post-vasectomy Screening Analysis (PVSA).

Limitations: Sample homogeneity is key for spermatozoa count.

Test Index

Chlamydia trachomatis PCR

Nucleic acid amplification test for the in-vitro qualitative detection of Chlamydia trachomatis

Sample Type: Vaginal/Rectal/Throat Swab or Urine samples in Cobas® PCR Media Tube

Limitations: Reliable results depend on proper sample collection, storage and handling procedures. Products containing carbomer(s), including vaginal lubricants, creams and gels may interfere with the test and should not be used during or prior to collecting urogenital specimens. Detection of C. trachomatis is dependent on the number of organisms present in the specimen and may be a ected by specimen collection methods, patient factors (i.e., age, history of STD, presence of symptoms), stage of infection and/or infecting C. trachomatis strain.

Neisseria gonorrhoeae PCR

Nucleic acid amplification test for the in-vitro qualitative detection of Neisseria gonorrhoeae.

Limitations: Reliable results depend on proper sample collection, storage and handling procedures. Products containing carbomer(s), including vaginal lubricants, creams and gels may interfere with the test and should not be used during or prior to collecting urogenital specimens. Detection of N. gonorrhoeae is dependent on the number of organisms present in the specimen and may be affected by specimen collection methods, patient factors (i.e., age, history of STD, presence of symptoms), stage of infection and/or infecting N. gonorrhoeae strain. N. gonorrhoeae may occasionally exchange genetic material with commensal bacteria commonly found in the normal microflora of the mouth and throat. It is possible that this exchange may include isolated DNA sequences which could, on rare occasion, produce a positive signal with this assay. Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform method correlation studies in their laboratory to qualify technology differences.

HSV-1/HSV-2 PCR

Real-time polymerase chain reaction for the in-vitro qualitative detection of Herpes simplex virus 1 and 2.

Limitations: Reliable results are dependent on adequate specimen collection, transport, storage and processing. False negative or invalid results may occur due to interference from various substances such as specimens containing blood in the amount greater than 40% of absorbed volume per swab may generate false negative results, specimens containing greater than 4.8 mg mucin per swab may generate false negative results, specimens containing greater than 1.6 mg feces per swab may generate false negative results, and specimens containing 20 mg or more of Vagisil Crème may generate false negative results. A positive result is indicative of the presence of HSV DNA and not necessarily viable viruses. A negative result does not rule out the presence of HSV due to insu cient DNA in the clinical sample. Mutations or polymorphisms in primer- or probe-binding regions may a ect detection of new or unknown variants, resulting in a false negative result with the cobas® HSV 1 and 2 Assay.

Test Index

Trichomonas vaginalis PCR

Nucleic acid amplification test for the in-vitro qualitative detection of Trichomonas vaginalis

Limitations: Reliable results depend on proper sample collection, storage and handling procedures. Products containing carbomer(s), including vaginal lubricants, creams and gels may interfere with the test and should not be used during or prior to collecting urogenital specimens. Detection of T. vaginalis is dependent on the number of organisms present in the specimen and may be affected by specimen collection methods, patient factors (i.e., age, history of STD, presence of symptoms), stage of infection and/or infecting T. vaginalis strain. Though rare, mutations within the highly conserved regions of the genomic DNA of T. vaginalis covered by cobas® TV/MG primers and/or probes may result in failure to detect the presence of the bacterium.

Mycoplasma genitalium PCR

Nucleic acid amplification test for the in-vitro qualitative detection of Mycoplasma genitalium

Limitations: Reliable results depend on proper sample collection, storage and handling procedures. Products containing carbomer(s), including vaginal lubricants, creams and gels may interfere with the test and should not be used during or prior to collecting urogenital specimens. Detection of M. genitalium is dependent on the number of organisms present in the specimen and may be a ected by specimen collection methods, patient factors (i.e., age, history of STD, presence of symptoms), stage of infection and/or infecting M. genitalium strain. Though rare, mutations within the highly conserved regions of the genomic DNA of M. genitalium covered by cobas® TV/MG primers and/or probes may result in failure to detect the presence of the bacterium.

Syphilis Multiplex PCR

Nucleic acid amplification test for the in-vitro qualitative detection of T. pallidum, HSV-1, and HSV-2.

Limitations: Reliable results depend on proper sample collection, storage and handling procedures. A negative result cannot exclude the presence of pathogens, if symptoms persist a further sample should be submitted.

Dried Blood Spots (DBS), for HIV/Syphilis/Hep A/Hep B/Hep C screening

Limitations: Due to the nature of the sample DBS can provide false negative results and if there is a high suspicion of infection, then a blood sample should be sent and not a DBS sample. Similarly, people who are known to be syphilis positive should not be tested using DBS as a full screen i.e. RPR cannot be performed on a DBS sample.

Contact the laboratory for further information regarding analyte specific limitations.

Turnaround Times

Routine, in-house sexual health samples are processed within **5 working days**.

Haematology and general biochemistry samples are processed and reported in **24 hours**.

Confirmation samples are processed within **14 working days**

Referral samples are processed within **14 working days**.

Post Vasectomy Semen Analysis takes place **on day of receipt**, with reporting up to **3 working days.**

The benefit of Acculabs Diagnostics being a Private Pathology Laboratory, is we can meet client requirements and desired turnaround times.

Acculabs offer a **PRIORITY SERVICE**, whereby urgent samples are processed and reported within 12 hours.

Contact **sales@acculabsdiagnistics.co.uk** to discuss your requirements.

Assessment and Monitoring

Quality and Key Performance Indicators (KPIs) - continuously monitored to enhance operational performances

Audits – the annual audit programme ensures conformity with the companies Quality Policy across the entirety of the business. This includes assessment of processes on a technical level but overall monitoring of the Quality Management System (QMS) also.

Non-conformances – incidents are recorded thoroughly, including root cause analysis to help ensure corrective action is effective against the true cause of any incident.

Trend analysis – carried out on a regular basis to ensure overarching themes and issues are addressed at the earliest opportunity.

Turnaround times – these are monitored consistently to ensure compliance with our contractual obligations and ensures the laboratory provides the best possible service to its customers.

EQA /IQC performance – monitored to ensure excellent performance and accuracy across all analytes in every department in the laboratory.

Post Vasectomy Semen Analysis

Acculabs Diagnostics perform Post Vasectomy Semen Analysis (PVSA) and Special Clearance.

PVSA is a test conducted after a vasectomy procedure to confirm if the vasectomy was successful in preventing sperm from being present in the semen.

A vasectomy is a surgical procedure where the vas deferens (the tubes that carry sperm from the testicles to the urethra) are cut, tied, or sealed. The purpose of the procedure is to make a man sterile, meaning he can no longer father children.

After the procedure, a post-semen analysis is done, usually 12-16 weeks later, to check the semen for the presence of sperm. This test helps to determine:

- Effectiveness of the vasectomy (it determines if sperm is no longer present in the ejaculate)
- Confirmation of sterility (if sperm is detected, this suggests the vasectomy was not completely effective and further steps may be needed)
- Typically, multiple semen analyses are done after the vasectomy to ensure sperm counts remain zero over time. If sperm is still present after a few tests, it may indicate the need for further treatment or another procedure.

Association of Surgeons in Primary Care

Acculabs work closely with the Association of Surgeons in Primary Care (ASPC) to maintain the appropriate service standards required for PVSA. Vasectomy is usually carried out free on the NHS in the community out of hospital, mainly GP surgeries and Sexual Health clinics (www.aspc-uk.net), or through Private Health Clinics.

Acculabs work with various customers to ensure the best possible service most useful to their needs and requirements.

Requesting PVSA Testing

Upon contract completion, there are two routes a client can request PVSA testing:

1. Manually, using a test request form
2. Electronically, using Acculabs' bespoke Vasectomy Portal, which reduces administration time, sends patient SMS reminders and automatically issues test kits to patient doors.

acculabs vasectomy PORTAL

Email:
sales@acculabsdiagnostics.co.uk
for further information on this.

Requesting Tests with accupath

Acculabs has developed its own bespoke Laboratory Information Management System (LIMs) for the requesting and reporting of tests.

AccuPath is a sophisticated .NET application. It is Microsoft based and has been built using Microsoft tools. It resides on Windows, therefore is accessible to a wide audience and it provides us with the means to adapt to client's needs.

It is a Secure Web Application – visible only on our internal network, therefore there is no requirement for installation on local devices.

Upon contract completion, we can on-board you to this system effortlessly to allow for a more streamline test requesting, reporting and invoicing experience. AccuPath is managed internally, therefore we have full control of training, accessing, developing and deploying updates.

Alternative Test Request Routes

Alternative route of requesting tests should be made electronically via the appropriate LIMS or via a physical form. A form template will be provided to you on contract completion, if this is your preferred choice.

Request form/LIMS information should be comprised of:

- Surname, or ID number*
- Forename, or ID number*
- Date of Birth
- Sample Collection Date*
- Sample Collection Time (to aid with sample stability)*
- Gender (to aid with biochemistry calculations)

- Clinician name (where applicable)
- Patient clinical details and treatment (where appropriate)
- Relevant tests required are requested (tick box)

If a test is not available to request on the form, please contact the laboratory to see if your test request is possible.

*Essential information for sample tube demographics in **red.**

Additional Requests

Additional/ further test(s) requests on samples previously received by the laboratory must be made within 72 hours. Requests will be processed if the sample stability is valid. Formal requests are required, whether it be made via email or a pdf request form.

Sample Rejection Criteria

Samples will be not be processed if:

- The sample does not contain the essential request information
- The sample(s) is unlabelled
- There is insuffcient volume in the sample tube
- The Cobas Swab sample has 2 swabs in 1 tube
- The Cobas Swab has no swab in the tube
- The sample is too old for analysis (refer to sample stability)
- The sample is broken or has leaked

Health and Safety

Acculabs Diagnostics UK Ltd has established its Health and Safety Policy to ensure the Health, Safety and Welfare at work of all employees and others who may be affected by its activities.

It is the policy of Acculabs Diagnostics UK Ltd to comply with the obligations under the Health and Safety at Work Act 1974.

This policy is implemented in all premises owned or controlled by the company and is applicable to all staff and visitors at our sites. This policy also applies to our staff working away from company sites.

In pursuance of this policy, the Company will take action to:

- Identify, assess, and manage the health and safety risks arising from our work activities.
- Consult with our employees and seek their cooperation on matters affecting their health and safety.
- Provide and maintain safe fixtures and equipment.
- Ensure safe handling and use of substances.
- Provide information, instruction, and supervision for employees.
- Ensure all employees are competent to do their tasks and to give them adequate training.
- Prevent accidents and cases of work-related ill health, so far as is reasonably practicable; maintain safe and healthy working conditions.
- Oversee the implementation and monitor and review this policy on an annual basis.
- Take disciplinary action for any breach of Company safety law.

acculabs DIAGNOSTICS

Thank You for Choosing Us.

www.acculabsdiagnostics.co.uk