INUVI
health data & insight

Guide for Laboratory Users

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Inuvi Diagnostics Ltd | Reg. number: 11304862 | Incorporated in England & Wales
Reg. address: Unit 10 Millars Brook Business Park, Molly Millars Lane, Wokingham, RG41 2AD

About Inuvi Diagnostics:

Inuvi Diagnostics offers state of the art clinical laboratory services designed to deliver exceptional quality combined with outstanding customer service. Our scientific expertise allows us to provide a quality-driven laboratory service that not only delivers routine and esoteric laboratory testing services.

Based in Gloucestershire, we offer a comprehensive range of tests providing our clients with the advantage of a single supplier for all pathology requirements.

Quality Assurance is a fundamental goal for Inuvi Diagnostics. Our quality management system includes requirements for internal quality control processes, in addition to ongoing participation in external quality assessment schemes:

NEQAS
Haematology
Parasitology
Immunology
Virology

DEQAS
Vitamin D

WEQAS
Routine and Esoteric Biochemistry (Blood & Urine)
POC Testing

LabQuality
Tumour Markers
Virology
STI Markers

Inuvi Diagnostics Limited is a UKAS accredited medical laboratory No. 10641, accredited to ISO/IEC 15189 and is Registered with the Care Quality Commission. This user guide includes details of the methods accredited at date of issue of this document (refer to the Routine Test List section).

Inuvi Diagnostics also holds UKAS accreditation for Flexible Scope under ISO15189 for:

- Biochemistry analytes and cancer markers using Roche Cobas e503 and e801, in serum only (capillary or venous) using manufacturer validated and CE marked kits.
- Virology/serology analytes using Beckman Access 2, Roche Cobas c503 and e801 and Dynex DS2. in serum (venous and/or capillary) using manufacturer validated and CE marked kits.

However, users should note that the schedule of accreditation is subject to ongoing change therefore a copy of our current schedule of accreditation can be accessed directly from the UKAS website (www.ukas.com) at any time, found by searching for our UKAS number 10641.

This guide has been compiled to provide users with clear information to assist on the provision of our services. For price enquiries, please contact sales@inuvi.co.uk.

Inuvi welcomes feedback from its customers, stakeholders and the end users of our services. If you have any suggestions as to how Inuvi might improve its services, please get in touch using the contact details in this guide.

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Advisory Services

This user guide has been compiled to provide service users with the information needed to collect and submit for testing the best quality and appropriate samples for each test; safeguarding informed consent at all times where required.

Inuvi Diagnostics is supported by a team of clinical consultants, in addition to medical and scientific professionals. The team are available to users to offer advice relating to:

- The most appropriate test or profile, including promotion of effective utilisation of services available
- Clinical indications and/or test limitations
- Testing frequency
- Advice on individual cases
- Professional judgements on the interpretation of test results
- Overcoming challenges to sample acceptance criteria (refer to Samples: Acceptance Criteria section)

For advice on any of the above, or information relating to the standard biological reference intervals and/or decision values used, or any other queries please contact Inuvi Diagnostics using the contact details shown in this guide.

Feedback

Feedback from laboratory users is welcomed and can support our commitment for continuous improvement. If you have any feedback which could be used to improve our management system, laboratory activities, services (including provision of information to aid in the selection of examination methods and the interpretation of examination results) you can get in touch using the contact details in this guide.

Contact Details

Inuvi Diagnostics is routinely open between 08:30 and 17:00 Monday to Friday (excluding Bank Holidays), Saturday 09:00 to 13:00 for sample reception. Our contact details are:

Tel: **+44 (0) 1452 226 125**
E-Mail: **laboratory@inuvi.co.uk**

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Data Protection

Inuvi Diagnostics will only require the personal data or information needed to provide the service requested.

Where we are provided with personal information Inuvi Diagnostics will keep this information secure, up to date and only retain for the minimum amount of time necessary, deleting it when it is no longer required. The data we hold is subject to our Control of Records Policy which defines the retention times for all records, we have taken guidance for these retention times from the Royal College of Pathologists.

Effective safeguards in place to make sure personal information is kept secure and in accordance with the GDPR. Full details of our Data Protection clauses are detailed in our standard Terms document (2.16).

You may at any time contact our data protection officer directly at dpo@inuvi.co.uk

All laboratories with a primary diagnostic role must report a confirmed notifiable organism to the UK Health Security Agency (UKHSA, previously Public Health England). To meet this regulatory requirement will require personal data to be shared with these public bodies in order to meet our legal obligations in accordance with Health Protection (Notification) Regulations 2010. For organism advice or service specific requirements please contact Inuvi Diagnostics using the contact details shown in this guide or refer to www.gov.uk/government/organisations/uk-health-security-agency

Test Reports

Inuvi test reports utilise a simplified test report format option permitted by accreditation standards. Therefore, reports may not include all the information on the report specified by an accreditation standard (i.e. ISO 15189:2022) but, as stated in the standard, this data is held by the laboratory and is available to the client on request.

Complaints Process

The satisfaction of our service users is extremely important to us, and we encourage open and transparent discussions regarding any concerns at any time, as it may be possible to resolve issues or concerns without the need for escalation to complaint. Where this has not been possible a complaint may be submitted in writing to your account contact or to **laboratory@inuvi.co.uk**. The complaint should contain sufficient detail and information to enable the complaint to be substantiated on receipt.

Complaints will be recorded and acknowledged within 5 working days of receipt with an investigating officer appointed. The investigating officer will normally be an individual who has not been involved directly in the activities to which the complaint relates.

Timescales for completing the investigation will vary dependent on the extent, complexity and severity of the issues detailed in the complaint. We do, however, aim to resolve most complaints within 1 working month of receipt.

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Samples

Samples: Request Forms and Labelling

Inuvi Diagnostics will supply request forms to users on request. The request forms and samples must be completed with a minimum of 3 (three) verified unique patient identifiers and all applicable supporting information (e.g. sample date):

- First Name
- Surname
- Date of Birth

Any samples and/or forms received that do not meet these requirements may experience a delay in results.

Note: we cannot routinely accept samples from individuals under 16 years of age.

In addition to the above, the following information is also important and should be verified and added either to the blood tube or the sample form, as relevant:

- Sample date and time
- Sex
- Sample source/site
- Details of the requestor and the location
- Fasting status, if clinically relevant
- Medication status, if clinically relevant
- Relevant clinical information, including family history where applicable
- High Risk Samples should be clearly identified on the form and individually packed

Request forms should be signed and dated by the individual taking the specimen

For blood group requests reference is taken from the Blood transfusion BCSH guidelines for the labelling of specimens and request forms which require the following mandatory details for all blood transfusion specimens and requests:

- A hand-written specimen and fully completed request form (handwritten or addressograph[1])
- Full name - correctly spelt
- Date of birth
- Sex
- Date and time specimen was taken
- Name of phlebotomist on the blood bottle and request form

Consent

It is the responsibility of the referring clinician to obtain all necessary informed consents, and/or permissions required (whether by law (including under the data protection legislation), good medical practice or otherwise) in order to permit the conduct of the Tests on the Samples. The referring clinician must ensure appropriate information is provided to all patients. Special counselling may also be needed for examination results with serious implications for the patient (e.g. for certain infectious diseases), it is the responsibility of the referring clinician to ensure applicable results are not communicated to the patient without the opportunity for adequate counselling.

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Samples: Volumes and Types

Inuvi Diagnostics can test both venous and capillary samples, and we specialise in capillary sample testing. For our up-to-date accreditation status refer to www.ukas.com.

Sample collection tubes should be correctly filled to the appropriate line. If in any doubt, please contact the Laboratory for advice.

For routine profiles one large Serum Separating Tube (SST) bottle will suffice, along with a fluoride oxalate and EDTA bottle. For additional immunoassays we recommend an additional SST sample be taken.

3-4 ml of EDTA blood is sufficient to perform routine haematology tests.

Any deviations, exclusions or additions to the requirements in this section should be recorded on the request form.

Code	Description
EDTA	EDTA
SST	SST
Citrate	Citrate
Oxalate	Oxalate
Lithium Heparin	Lithium Heparin
Trace Metal	Trace Metal
Red	Plain serum (capillary)
BC	Blood Culture
X	Special container – contact the laboratory
RF	Random Faeces
FC	Faeces Collection
RU	Random Urine
FCRU	First Catch Random Urine
CU	30ml Aliquot from a 24-hour Urine Collection – State Total Volume
AU	30ml Aliquot from a 24-hour Urine Collection with 10ml of 0.1N Hydrochloric Acid Added – State Total Volume
EMU	Early Morning Urine
LC	60ml Container
TVP	Cytyc Thin PrepVial
STM	Orange/Blue Swab for Culture in Transport Medium
CS	Charcoal Swab
GVS	Green Viral Swab
PCR	PCR Swab for Infection Screening
UCYT	Urine Cytology Container
DBS	Dried Blood Spot
QFIT	Faecal Immunochemical Test Kit
Sodium Heparin	Sodium Heparin (Trace Metal)

Helpful Advice for Sample Collection:

- Aim to fill specimen tubes completely
- Never swap the caps of the containers as this may also transfer additives and cause misleading results or rejected samples
- Never pour blood from one specimen container to another because transfer of inappropriate additives will cause misleading results or rejected samples

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The materials used for sample collection, such as needles, should be disposed of as clinical waste in line with your local procedures. **Needles must never be sent with samples to the laboratory as it puts the public, the sample transport company (e.g. Royal Mail) and our staff at risk.**

For capillary samples the table below offers sample volume guidance for serum samples, please contact the Laboratory for specific volume advice to meet your testing needs.

Analyte/Profile	Volume of serum (approximate) µl
SST capillary Collection Dead Volume	50
Lipid	6.5
VIT D	12
LFTs	19
B12 (total)	9
Testosterone	12
Iron Profile	35
Basic Thyroid	40
hs-CRP	2
Advanced thyroid	70
Hba1c (whole blood)	100
Omegas (whole blood)	100
Full Blood Count (whole blood)	100
Folate	15
Uric Acid	2.5
Insulin	6
Active B12	18
DHEAS+	9
Oestrogen	15 (not recommended for capillary SST serum)
Progesterone	12 (not recommended for capillary SST serum)
FSH	24
LH	15
Prolactin	15
SHBG	15
Ferritin	10

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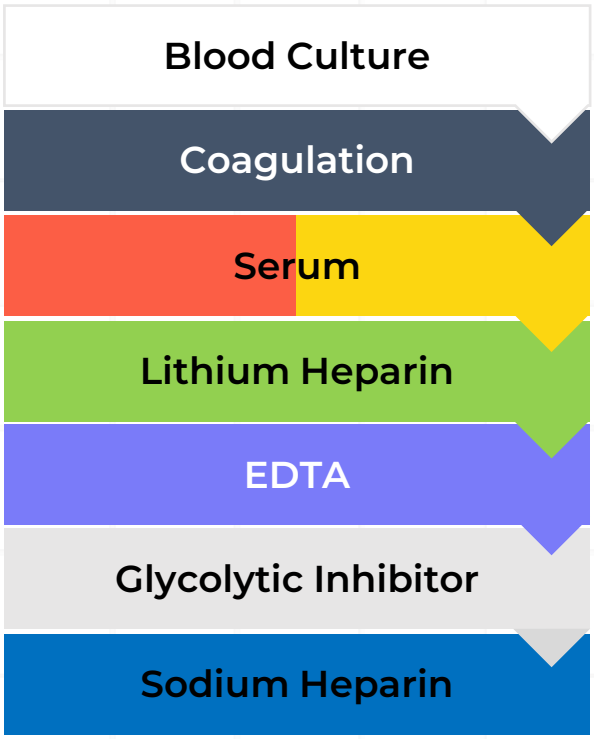
Samples: Blood Draw Order

CLSI Recommended (GP41*)

If a winged blood collection set is used, the first tube in the series will be underfilled. Therefore, if a coagulation specimen is drawn first, a discard tube (a no additive or coagulation tube) is recommended to be drawn prior to this tube to ensure the proper anticoagulant-to-blood ratio.

Note: Follow your facility's protocol for Order of Draw.



Cap Colour	Tube Type	Number of Inversions
White	No Additive	N/A
Blue	Coagulation	4
Red	Plain Serum Tube	5 – 10
Green	Lithium Heparin	5 – 10
Lavender	EDTA	8 – 10
Grey	Glycolytic Inhibitor	5 – 10
Gold	Serum Separator Tube (SST)	5 – 6

*Reproduced with permission from CLSI. H41-A6. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Sith Edition. Copies of the current edition may be obtained from Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne Pennsylvania 19087-1898, USA. Internet: www.clsi.org.

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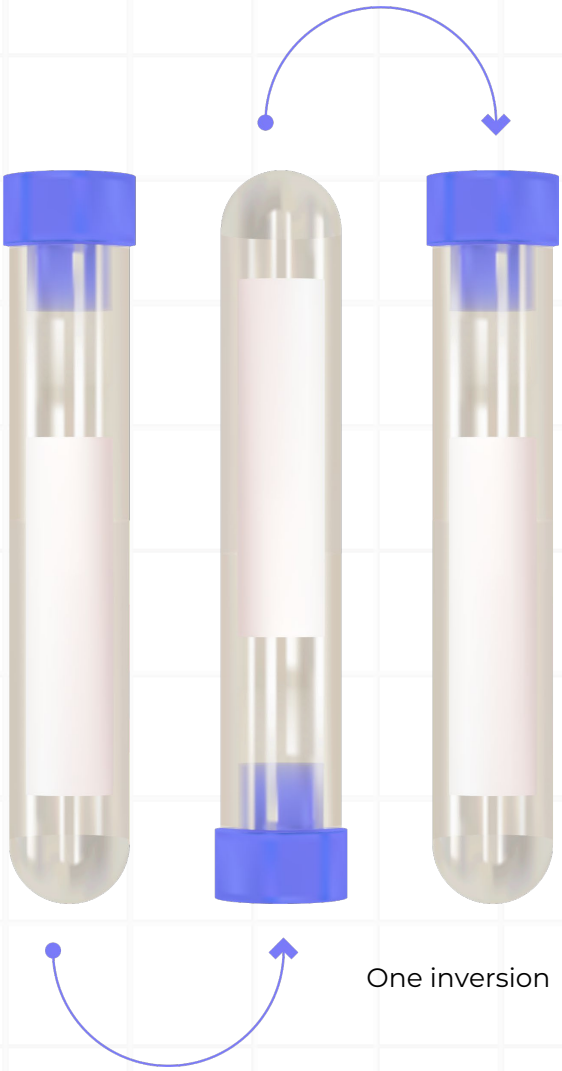
To achieve the proper mix of additive and blood, each tube must be gently inverted as it is removed from the holder.

One complete inversion

Turn the filled tube upside down and return it to an upright position

Repeat required number of times for each tube type



One inversion

Importance of mixing

Insufficient or delayed mixing of serum tubes may result in delayed clotting

Inadequate mixing of anticoagulant tubes may result in platelet clumping, clotting or incorrect test results

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Samples: Specific Requirements

The specific requirements listed below correspond with the Sample Type/ Specific Requirements shown in the Testing sections of this user guide.

Information relating to collection of capillary samples is available, please contact the Laboratory for advice or refer to the Collecting a Finger Prick Sample section of this guide.

#	Specific Requirements
1	Please contact the laboratory for special sample containers/instructions/tubes
2	Confirmation of non-negative drugs screen by LCMS may take up to 3 days for saliva/urine and 5 days for hair samples
3	Please provide clinical history and protect from light
4	Please send to the laboratory ASAP
5	Please do not send the sample to the laboratory between Thursday and Monday
6	Please contact the laboratory before taking and sending the sample
7	Please separate and freeze the sample if sending overnight
8	For Quantiferon Gold analysis the samples should arrive in the laboratory within 16 hours or be incubated overnight before being sent
9	Please provide clinical history
10	SST recommended for venous samples only, for capillary samples advise use plain serum (red top)
11	Patient consent required
12	Please provide one sample for each person being tested
13	Please protect the sample from light
14	Please provide details of the patients travel history
15	For Ammonia analysis only – please provide frozen EDTA plasma only (ensure the patient is fasted, avoid smoking)
16	For Lactate analysis only – please provide frozen fluoride oxalate plasma
17	For Homocysteine – samples should be spun and separated within 1hour of venepuncture
18	For Renin – samples must be collected either upright/active or resting/surpine (3 hours testing)
19	For coagulation studies – please ensure sample arrives in the laboratory within 4-8 hours. If a delay in transportation is expected then citrate samples should be double spun, separated and frozen within 4-8 hours of sample collection
20	Please include patients age, height and weight
21	For sample types (FRCU/PCR Swab/TPV or Semen)

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#	Specific Requirements
22	Please use a Urine Cystology container (ideally first catch, mid-morning specimen)
23	Please provide a fresh sample
24	Please collect the sample at the end of the working day
25	Please collect the sample at the end of exposure
26	Please ensure the sample label is handwritten with forename, surname and date of birth
27	Please provide sample date and time
28	Please ensure patient has fasted for at least 8 hours
29	For urine Schistosoma please provide 25ml terminal urine taken between midday and 3pm

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In addition to the above information, there are a number of specific variables to consider dependent on the test to be performed:

Pre-Analytical Variables – Biochemistry

- Patient preparation – prior to collecting specimens for chemistry, certain patient variables need to be considered. For certain chemistry analytes, fasting maybe required however it is now widely accepted that fasting for glucose and lipids in the general population is not essential as glucose, cholesterol and triglyceride levels return to normal after 5-6 hours post food intake. Therefore, fasting may not be required (Langsted et al 2008). It is recommended that fasting decisions be made on a case-by-case basis, refer to NICE clinical guideline CG181
- Other analytes, such as cortisol, testosterone, TSH, have diurnal variations, where the analyte is at its highest level in the morning and the levels gradually decrease during the course of the day
- Selecting the site – selecting the appropriate site for venipuncture can contribute to a better- quality sample. The preferred site is the median cubital vein
- Site preparation – prior to venipuncture, the site should be cleansed with alcohol. Cleansing starts at the centre of the vein and should continue outward in concentric circles. Before performing the venipuncture, the alcohol should be allowed to air dry. This will help to ensure that the specimen is not contaminated with alcohol, as this can lead to haemolysis and falsely raised blood alcohol levels
- Haemolysis can result in a spurious increase of serum/plasma analytes including potassium, total protein, AST, ALT, CK, phosphate, Lactate Dehydrogenase (LDH), urea, iron, folate and magnesium. Whereas albumin, ALP, GGT, chloride, glucose, sodium and insulin can be falsely lowered
- Tourniquet application and time – the tourniquet should be applied approximately three to four inches above the venipuncture site. The tourniquet should be on the arm no longer than one minute. Prolonged tourniquet time can lead to an increase in various chemistry analytes, including serum protein, cholesterol, triglycerides, potassium and lactic acid

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- Order of draw – following the correct order of draw during venipuncture will help to ensure accurate test results. Please see above for Order of Draw for Multiple Tube Collections Document.
- Proper tube mixing – all tubes with additives need to be inverted to mix the additive evenly with the blood. Plastic serum tubes and BD SST™ tubes contain clot activator and should be inverted five times to mix the activator with the blood and help the specimen clot completely. Other additive tubes, such as heparin, need to be inverted 8-10 times to mix the anticoagulant with the blood and prevent clotting. Be sure that tubes are not being shaken vigorously as this can lead to a haemolysed sample
- Correct specimen volume – all blood collection tubes need to be filled to the correct volume. This will ensure the proper amount of blood for the amount of additive in the tube (blood to additive ratio)
- Expiration dates should also be checked on the evacuated tubes. Expired tubes should not be used as they may have a decreased vacuum, as well as potential changes in any additives in the tubes

Pre-Analytical Variables – Haematology / Coagulation

- Tubes should be checked for proper blood fill volumes and appropriate action should be taken if tubes are under-filled
- Blood smears for differentials from acceptable specimens should be prepared as soon as possible
- Blood counts from acceptable venipuncture specimens should preferably be performed within 24 hours of collection. FBC samples are acceptable up to 3 days post venipuncture however certain parameters, e.g. MCV, MCHC, RDW, HCT and WBC differential, maybe affected by delayed analysis
- Coagulation analysis should preferably be performed within four hours of collection, unless samples are double spun, separated and frozen for transport. Please call the laboratory for further information
- Please include anticoagulant information when requesting coagulation studies
- Under-filling the EDTA blood collection tube can lead to erroneously low blood cell counts and haematocrits, morphologic changes to RBCs, and staining alteration
- Conversely, overfilling the blood collection tube will not allow the tube to be properly mixed and may lead to platelet clumping and clotting
- We recommend tubes are filled to ± 10% of the stated draw volume
- White blood cell (WBC) and platelet counts can be affected by cryoglobulins. Cryoglobulins aggregate and may be falsely identified as platelets and/or WBCs by the haematology analyser. Cold agglutinins have been known to cause spurious reporting of macrocytosis and decreased RBC counts
- Platelet satellitism is a phenomenon that only occurs in EDTA anticoagulated blood. This is due to EDTA-dependent IgG autoantibodies and occurs at room temperature. When platelet satellitism is present there may be a false elevation of cell counts. In this instance a citrate sample maybe requested

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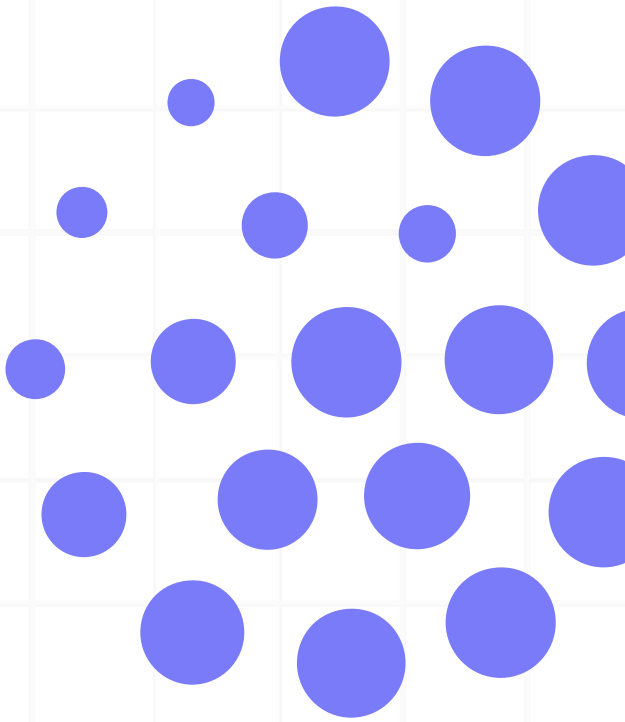
Handling of Blood Specimens Post Collection

- Certain chemistry analytes will require the tube of blood to be chilled after collection in order to maintain the stability of the analyte. A slurry of ice and water is recommended for chilling the tubes of blood. In these cases, it is recommended that you contact the laboratory
- Examples of specimens that need to be chilled or transported on ice include adrenocorticotropic hormone (ACTH), ammonia, catecholamines, free fatty acids, renin and aldosterone. Please see Test Index for further information
- Other analytes are photo-sensitive and need to be protected from light in order to remain stable and to ensure that the laboratory reports an accurate result. This can be done by wrapping the tube of blood in aluminium foil
- The most common example of a light-sensitive analyte is bilirubin. Other chemistry analytes that need to be light protected include beta-carotene and erythrocyte protoporphyrin
- Stability for whole blood, serum and plasma. Ideally a whole blood specimen would be centrifuged and separated before postage, e.g. by using a SST tube, however we appreciate this is not always possible. It is therefore important to know that some analytes are affected by delays in transit if un-spun; these include but are not limited to: AST, LDH, Sodium, Chloride, Potassium, Bicarb, Calcium, Phosphate and Insulin. As such these are not recommended for postal samples.



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Pre-Analytical Variables in Urine Testing – Biochemistry

Timed specimens provide the most valuable information for the concentration of a specific analyte. The most common influences on urine biochemistry results are preservatives, diet and medication. More specifically, some of the drugs and foods that affect urine chemistry results are as follows:

- Sodium is influenced by diet. Increased sodium results can be caused by antibiotics, cough medicines or laxatives. Decreased sodium results will be seen with diuretics
- Potassium can also be influenced by diet. Increased measurements can be seen with diuretics, salicylates or glucocorticoids
- Chloride is falsely decreased by androgens, estrogens, methyldopa, or cortisone. It is falsely increased by bicarbonates or corticosteroids
- Creatinine is increased by gentamycin or heavy metal chemotherapeutic agents
- Calcium shows increases by antacids, anticonvulsants, and some diuretics, while adrenocorticosteroids and oral contraceptives cause decreases
- Urine total protein is affected by alcohol, anti-inflammatory drugs, salicylate and warfarin
- Bilirubin is decreased by light and ascorbic acid and can be increased with antibiotics, diuretics, oral contraceptives, sulfonamides, and steroids
- 5-HIAA is influenced by many types of foods (see Test Index). It is recommended those listed are not eaten three days prior to testing
- Porphyrins are affected by light, morphine, oral contraceptives, and sulfonamides. Some of these also apply to porphobilinogen
- Catecholamines are influenced by chocolate, cocoa, coffee, tea, bananas, and vanilla. They are also affected by stress and exercise. They can be increased by lithium, insulin, tetracycline, and nitroglycerin. Catecholamines can be decreased with salicylates and imipramine. These same factors also affect VMA, a metabolite of catecholamines
- It is important that the total urine volume be collected and recorded during the time period in order to correctly calculate the analyte concentrations

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Pre-Analytical Variables in Urine Testing – Microbiology

- Please ensure samples for MC&S are taken into a clean boric acid container (red topped urine container), these are for urine microbiology only
- Ensure the sample lid is hand tight
- For urine microbiology please provide a midstream clean catch specimen, an MSU is less likely to produce contaminants compared to a random urine sample
- Be aware of extraneous sample contamination, hands, skin, and clothing. Sample collection should be aseptic. The inside lid or rim of the sample container must not be touched by hands or skin
- False-negative growth may be seen in specimens submitted from patients who are taking antibiotics

Centrifugation

- A swinging bucket centrifuge is preferred for centrifugation and the tubes should be spun for ten minutes at a speed of 1100 to 1300 relative centrifugal force (RCF). A 15-minute spin at the same speed is required for spinning tubes in a fixed-angle centrifuge. Serum and plasma tubes without gel can be spun at a speed of 1000 RCF for 10 minutes.
- It is important to spin gel tubes for the recommended time. The gel barrier in the tubes needs time to move and form a solid barrier between the red cells and the serum or plasma.

  If the tubes are spun for less than the recommended 10 minutes cells may remain in the plasma and could cause interference with some chemistry analytes
- It is recommended that SST tubes should not be re-centrifuged after their initial centrifugation. Re-spinning the tubes can result in some biochemical indices being elevated as excess serum that has been in contact with the red cells will be forced from underneath the gel barrier into the serum

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References

- www.bd.com/en-us/offerings/capabilities/specimen-collection/vacutainer-educational-services-and-materials/labnotes

- Bonini P, PlebaniM, Ceriotti F, et al. Errors in laboratory medicine. Clin Chem. 2002; 48:691-698.
- NCCLS - Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard, Fifth Edition, H3-A5 Vol. 23 No. 32, December 2003.
- NCCLS - Tubes and Additives for Blood Specimen Collection; Approved Standard-Fifth Edition, H1- A5 Vol. 23 No. 33, December 2003.
- BD Evacuated Blood Collection System Package Insert 6/2004
- NCCLS - Procedures for the Handling and Processing of Blood Specimens; Approved Standard-Third Edition, H18-A3 Vol. 24 No. 38, November 2004.
- NICE clinical guideline CG181 Lipid modification Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease

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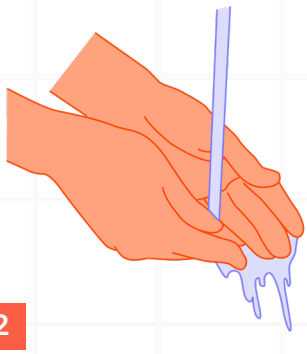
Samples: Collecting a Finger Prick Sample

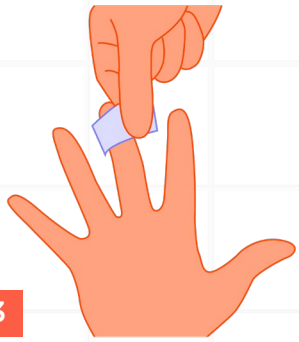
1

The best location for collecting a finger prick sample is from the side of your middle finger or ring finger (see shaded area). Open the pack of lancets.



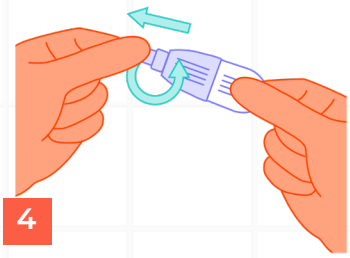
2

Wash your hands in warm soapy water. It is much easier to collect your sample if your hands are warm. Dry them thoroughly with a clean, dry towel.



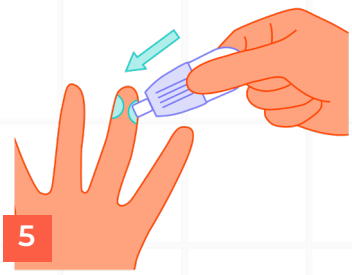
3

Using the Alcohol Swab clean the selected finger. Wipe dry with a clean tissue. Be sure your finger is completely dry as blood will not form a drop at the puncture site of a moist finger.



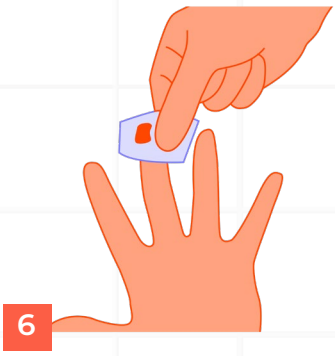
4

Remove one of the lancets from the bag. Twist and remove the blue stick. The lancet is ready to use.



5

Sit down when collecting your blood drops. Position the lancet against the side of your chosen finger. The lancet will activate in one step only when positioned and pressed firmly against the skin until a click is heard. Should you need to repeat the process to help obtain enough blood use one of the remaining lancets.



6

This will puncture the skin and a small drop of blood will form. Wipe away the first drop of blood with a tissue.

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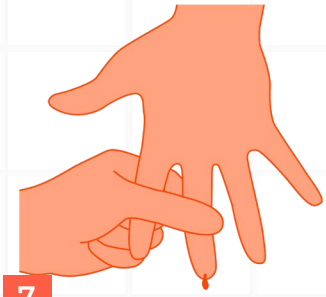
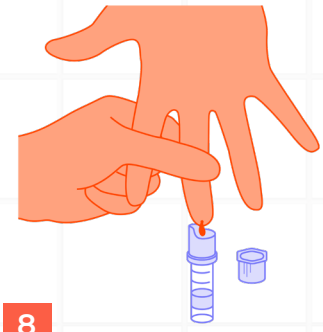
Samples: Collecting a Finger Prick Sample



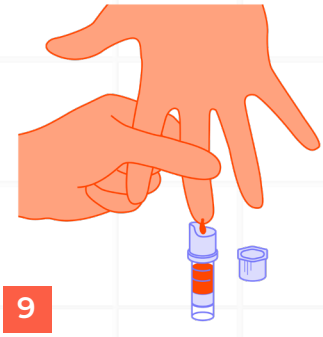
7

Holding your hand/arm downwards, firmly massage your hand down to your finger to encourage blood flow.



8

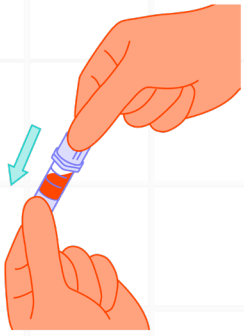
Take your finger with the other hand and gently milk your hand and finger to help the blood drop into the blood collection tube as shown.



9

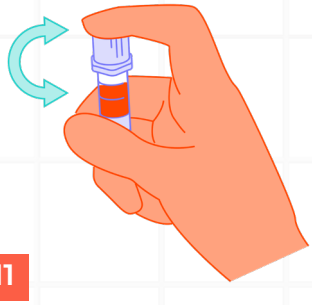
Fill the blood collection tube to the upper line on the side of the tube.

NB: If you are unable to collect enough blood use the second lancet on a middle or ring finger on the other hand. Alternatively, try wiping the finger you have been using with a dry tissue. Pause for 5-10 seconds and blood drops are likely to reform, and you can then start collecting again.



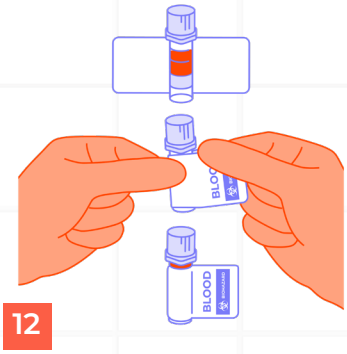
10

Once you have filled up to the top fill line, or even just over, stop collecting, clean the finger with a wipe and apply the supplied spot plaster to stop the bleeding. Then push on the cap of the blood collection tube securely until you hear an audible click to confirm closure.



11

Once you have replaced the cap, gently invert the collection tube 5 to 10 times.



12

Make sure your tube is labelled with your details using the blood collection tube label supplied. This is very important as unlabelled samples cannot be accepted.

Affix the label by placing the tube in the middle of the label and wrapping the label around the tube.

Place the collection tube back into the clear case provided.

Once collected the sample/s should be dispatched to us using envelopes supplied with your kit. Always ensure the laboratory request form is completed and enclosed with the sample/s.

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Capillary Sample Testing

Inuvi Diagnostics specialises in testing Capillary/Finger prick samples and as such we have undertaken robust verification procedures to ensure the assays we offer for capillary compare to those for venous samples.

There are numerous benefits to using capillary sampling instead of venous samples, these include the fact that they can be self-collected, the patient can time sampling to fit around their lifestyle, and the method uses less material and therefore creates less waste.

However, to ensure comparability we have not only verified that the assays offered for capillary samples compare to those offered for venous samples, but that those analytes are also stable in the post for a practicable period.

Our research has identified that some analytes may not be suited to capillary analysis, due in the main to issues relating either to the method of collection, i.e. finger prick and the process of forcing blood through tissue. To this end we have listed below those where there may be some guidance required:

1. Analytes adversely affected by haemolysis

   a. AST
   b. LDH
   c. CK
   d. Calcium
   e. Iron
   f. Folate
   g. Magnesium

Those analytes listed above are sensitive to haemolysis, therefore failure rates due red cells being damaged during the process of sample collection or during transit can be high. If a sample is taken without damage to the red cells, then these analytes if tested within a given time period are both accurate and stable.

2. Result affected by the collection process

   a. FBC
   b. HbA1C

Those analytes listed in section 2 are sensitive to sample clotting during the collection process, this may be due to the capillary blood 'sitting' too long on the tissue before entering the collection tube, or a lack of mixing when in the tube. Average failure rates are approximately:

- HbA1C 10%
- FBC 20-30%

but can be improved upon with improved technique.

3. In addition, some analytes are unstable if not spun (centrifuged) within 6-8 hours after collection, making them unsuitable for postal capillary samples, these include:

   a. Phosphate
   b. Sodium
   c. Chloride
   d. Potassium
   e. Insulin
   f. Bicarbonate

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Handling of Capillary Samples

- Certain chemistry analytes show greater variability in SST capillary tubes than in the corresponding venous tubes, these include some sex hormones including Oestradiol, Progesterone and to a smaller extent Testosterone.
- These analytes show a negative bias in capillary SST as compared to venous SST or plain serum tubes (capillary and venous). Our research proposes that this is due to the greater blood/gel ratio seen in capillary tubes.
- Therefore, we recommend using plain serum (RED topped) capillary tubes for sex hormones. Please contact the laboratory for more information.
- There are numerous variables to consider when collecting capillary samples. This is due to the fact that blood comes into direct contact with the skin and as such anything present on the skin could end up in the capillary sample. For instance, we have identified that certain creams can affect lipid results, others that contain tints (Iron Oxide) can affect Iron results. While creams that contain Biotin can interfere with immunoassay tests.
- In addition, anything that is absorbed into the capillary network via the skin will be present in very high concentrations within the capillary sample, e.g. HRT.
- It has been shown that hand washing removes approx. 70% of materials on the skin surface, therefore care should be taken when collecting capillary samples when creams, make up, etc have been used as residual amounts may still be present after one wash.
- Different manufacturers have different sized capillary collection tubes, Greiner provide a 800ul tube, both Red and SST capillary tubes, while BD provide a 600ul SST tube and a 500ul Red topped tube. We have verified analytes using these two manufacturers, in addition we have also verified some analytes using the Tap II collection device.
- Please contact the laboratory to discuss or refer to our UKAS schedule.

NB.

- Some analytes show a negative bias in capillary SST tubes. We recommend plain serum (RED topped) capillary tubes for Oestradiol and Progesterone.
- Capillary samples are prone to contamination with topical products e.g. HRT
- Some creams can also affect laboratory results from capillary samples e.g. Lipid's,

If you have any concerns please discuss with the laboratory.

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Samples: Transportation

Samples should be sent to the laboratory using the Royal Mail Track24 system. Sample can also be delivered using couriers.

Samples should be packaged and labelled “Biological Substance – Category B” with the UN3373 diamond or packaged to prevent damage or leaks and labelled “Fragile – Exempt Human Specimen”.

The sample container (primary packaging) should be placed into plastic container / transporter / clam shell (secondary packaging) with absorbent material in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packages must be secured in outer packaging.

Needles must never be sent with samples to the laboratory as it puts the public, the sample transport company (e.g. Royal Mail) and our staff at risk.

Inadequately packaged and labelled samples may be rejected by Royal Mail or the courier company.

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Samples: Acceptance Criteria

Every sample received at Inuvi Diagnostics is checked to ensure it meets the acceptance criteria for the requested laboratory testing.

Sometimes the requested tests cannot be processed if the samples don't meet the required criteria. In these cases, the laboratory may need to reject the samples, and may not be able to carry out the testing.

Requesters will also be notified where the integrity of the sample may have been compromised during transport or is considered to have risked the safety of the delivery service, the general public or laboratory staff. Should this occur, guidance on how to prevent such a risk for future samples will be provided.

In some cases, it may be possible to rectify the issue, but turnaround times may be affected.

Frequent sample rejection examples include:

- Incorrect sample types received
- Samples without the appropriate preservative
- Samples not transported in appropriate conditions (e.g. frozen samples)
- Samples in incorrect containers
- Insufficient sample received
- No sample received
- Labelling or form issues (mislabelled / unlabelled / no forms/ no clinical information)
- Clotted / haemolysed /lipaemic /icteric samples
- Sample is broken or has leaked in transit
- Stability time has been exceeded. Stability time is test dependant so 'old' samples may not be viable for the requested test (reported as DELAY)
- Sample adversely affected by postal conditions/time delay (reported as AGED)
- Sample contamination (e.g. being in the same bag as a leaking sample).
- Samples are high risk or infectious.
- Samples that are received in expired tubes.

In circumstances where the sample is considered critical or non-repeatable, the laboratory may choose to process the sample, and will issue a final report indicating the nature of the problem, and where applicable, that caution is required when interpreting the result.

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Samples: Stability

Inuvi Diagnostics have performed a number of research projects to ascertain sample stability in unseparated samples over prolonged transit times and at different temperatures.

Initial verification studies focussed on ambient temperatures, however additional studies have been performed for most analytes over a worst-case scenario temperature profile, this includes 24 hours each at 2-8°, ambient and 30-37°C.

Approximately 98% of samples arrive in the laboratory within 3 days using our tracked 24 postal kits, we have therefore focussed our stability testing methodology over this time frame, however additional studies have also included time frames up to 7 days.

Samples should be dispatched to the laboratory as soon as possible to protect the integrity of the sample. However, there are times when this isn't possible, if in any doubt we recommend checking with us using the contact details.

Samples: Storage

The laboratory retention time of samples follows guidance from the Royal College of Pathologists.

As a guide samples are kept for 7 days after the final report has been released.

Under certain circumstances, it is possible to add tests on to samples that are already in the laboratory, but this will depend on sample stability, tube type and, for some tests, there will be timing restrictions ,e.g. FBC, LDH. All add-on requests must be confirmed in writing to Inuvi Diagnostics within 24 hours of request ensuring the patient/sample IDs are provided.

Please Note: There may not be sufficient specimen to perform the additional tests. Investigations are best performed on fresh primary specimens and where possible, any non-urgent investigations should be deferred until a fresh sample can be collected.

Should additional tests be required please contact the laboratory as soon as possible to avoid disappointment.

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Testing: Measurement Uncertainty

Laboratories are responsible for ensuring that test results are fit for purpose by defining analytical performance goals and selecting appropriate measurement procedures. All types of measurement have some inaccuracy due to bias and imprecision; therefore, measurement results can only be estimates of the values of the quantities being measured.

To properly use such results, laboratories and their users need some knowledge of the accuracy of such estimates.

Evaluating measurement uncertainty is an accreditation standard requirement.

Inuvi Diagnostics performs assays in accordance with the manufacturers' instructions. Measurement uncertainty, which has been estimated for each assay during the verification procedure, is reviewed at regular intervals to ensure that uncertainty values do not exceed the pre-defined maximum allowable uncertainty for each assay. Overall assay performance is also regularly monitored through internal quality control (IQC) and external quality assessment (EQA) schemes and incorporated in test result interpretation. Measurement uncertainty for individual assays is available upon request.

Testing: Turnaround Times

Consistent achievement and the improvement of published target turnaround times is a priority objective for Inuvi Diagnostics. Our performance is monitored closely as a key performance indicator to support our quality objectives.

Current turnaround times are detailed throughout this user guide, with the turnaround time quoted calculated from the time of sample receipt in the laboratory. Results are reported once all requested tests are complete, this may delay reporting where one test takes longer than others on the same patient request form; interim reporting is available on request to expedite completed tests, please contact the laboratory if you require interim reporting.

All turnaround times are quoted as working days (i.e., Monday to Friday) unless otherwise specified.

Tests subject to UK Health Security Agency reporting will be referred for confirmation testing prior to release of the results, therefore the turnaround times quoted in the Routine Test List section may be extended where the confirmation test is necessary.

For anti-HBs tests, an antibody level below 10mIU/ml (<10IU/L) is classified as non-response to vaccine, and testing for markers of current or past infection is good clinical practice. Therefore, our standard process is to automatically reflex Hepatitis B Surface Antigen and Hepatitis B Core Antibody should there be a Hepatitis B Surface Antibody result of <10IU/L, which will extend the turnaround time (and may also require referred confirmation).

For related information on UKHSA refer to www.gov.uk/guidance/notifiable-diseases-and-causative-organisms-how-to-report

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Testing: Referrals

For some specialist testing Inuvi Diagnostics may refer to laboratories that have the specific expertise with the methods used. Wherever possible we endeavour to use accredited laboratories, details of a referral laboratory used is available on request. Referred tests are indicated in the Routine Test List in this user guide and will also be denoted on test reports by the # symbol.

Testing: Routine Profiles

Profile Name	Components	Sample Type/ Specific Requirements	TAT
Iron Status Profile (ISP)	• Iron • Iron Binding Capacity (Total) • Iron Binding Capacity (unsaturated) • Transferrin Saturation • Ferritin	SST	24 hours
Kidney Function Profile (KF)	• Creatinine • Urea • Estimated GFR	SST	24 hours
Lipid Profile (LIPP)	• Triglycerides • Cholesterol • HDL Cholesterol • HDL % of Total • LDL Cholesterol • Non-HDL Cholesterol	SST	24 hours
Liver Function Test (LFT)	• ALT • AST • Total Protein • Alkaline Phos • Albumin • Bilirubin • Globulin • Gamma-GT	SST	24 hours
Thyroid Function Profile 3 (TF3)	• Thyroid Stim. Hormone • Free T3 • Free Thyroxine (FT4)	SST	24 hours
Full Blood Count (FBCX)	• Haemoglobin (g/L) • Hct • Red Cell Count • MCV • MCH • MCHC (g/L) • RDW • Platelets • MPV • White Cell Count • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils • Neutrophils % • Lymphocytes % • Monocytes % • Eosinophils % • Basophils %	EDTA	24 hours

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Testing: Routine Test List

*Accreditation statuses correct at date of issue, refer to www.ukas.com https://www.ukas.com/find-an-organisation/ for current schedule of accreditation (UKAS Medical Laboratory 10641).

Test	Test Code	TAT	Sample Type/ Specific Requirements	Referral Test (Y/N)	ISO 15189 Accredited test* (Y/N)
Active Vit B12 (holotranscobalamin)	AB12	24 hours	SST	N	Y (venous & capillary)
3A Food Allergy	3A	5 days	SST	Y	N
Albumin	ALB	24 hours	SST	N	Y (venous & capillary)
Aldosterone	ALDN	10 Days	SST	Y	N
Alkaline Phosphatase (ALP)	ALP	24 hours	SST	N	Y (venous & capillary)
ALT (Alanine Aminotransferase)	ALT	24 hours	SST	N	Y (venous & capillary)
Amylase	AMY	5 Days	SST	Y	N
ANCA (Anti-Neutrophil Cytoplasmic Abs)	ANCA	5 Days	SST	Y	N
Angiotensin Converting Enzyme	ACE	5 Days	SST	Y	N
Anti-Mullerian Hormone	AMH	24 hours	SST	N	(accredited under Flexible Scope for venous & capillary)
Antinuclear Antibodies	ANA	5 Days	SST	Y	N
Apolipoprotein A1	APOA	24 hours	SST	N	Y (venous & capillary)
Apolipoprotein B	APOB	24 hours	SST	N	Y (venous & capillary)
AST (SGOT)	AST	24 hours	SST	N	Y (venous only)
17-Beta Oestradiol	OEST	24 hours	Serum [10]	N	Y (venous & capillary)
Beta HCG (Quantitative)	QHCG	5 days	SST	Y	N
Bicarbonate	HCO3	5 days	SST (spun)	Y	N
Bilirubin (Total/Indirect)	BILI	24 hours	SST	N	Y (venous & capillary)
Bilirubin (Direct)	DBIL	5 Days	SST	Y	N
Blood Group	ABO	5 days	EDTA [26]	Y	N
BNP (NT-pro BNP)	BNP	3 days	SST	N	Y (venous & capillary)
Borrelia Antibodies (Lyme Disease) IgG, IgM	BORR	5 days	SST [9, 14]	Y	N
Lead (Blood)	LEAD	10 Days	EDTA	Y	N
C Peptide	R_CPEP	7 days	SST	Y	N
CA 125	CA125	24 hours	SST	N	N
CA 19-9	CA199	24 hours	SST	N	N
Calcium	CA	24 hours	SST	N	Y (venous only)
Adjusted Calcium	CCA	24 hours	SST	N	Y (venous only)
Calprotectin	CALP	10 days	RF	Y	N
Carcino Embryonic Antigen	CEA	24 hours	SST	N	N
Ceruloplasmin	CERU	5 days	SST	Y	N
Chloride	CL	24 hours	SST	N	Y (venous only)

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Test	Test Code	TAT	Sample Type/ Specific Requirements	Referral Test (Y/N)	ISO 15189 Accredited test* (Y/N)
Carbohydrate Deficient Transferrin (CDT)	CDT	7 days	SST	Y	N
Cholesterol	CHO	24 hours	SST / Lithium Heparin	N	Y (venous & capillary)
Cholinesterase (Serum/Pseudo)	CHPS	5 days	SST	Y	N
Copper (Serum)	COPP	10 days	SST	Y	N
Cortisol	CORT	24 hours	SST	N	Y (venous only)
C Reactive Protein (High Sensitivity)	CRP	24 hours	SST	N	Y (venous & capillary)
Creatinine	CREA	24 hours	SST	N	Y (venous & capillary)
Creatine Kinase	CKNA	24 hours	SST	N	Y (venous only)
DHEA Sulphate	DHEAS	24 hours	SST	N	Y (venous & capillary)
Enteric Organism Rapid Detection	EORD1	5 Days	RF	Y	N
ESR	ESR	24 hours	EDTA	N	N
Faecal Occult Blood Test (Faecal Immunochemical Test/FIT)	QFIT	3 days	QFIT (Contact the lab directly to confirm)	N	N
Ferritin	FERR	24 hours	SST	N	Y (venous & capillary)
Folate (Serum)	FOLA	24 hours	SST	N	Y (venous only)
Follicle Stim. Hormone	FSH	24 hours	SST	N	Y (venous & capillary)
Free Androgen Index	FAI	24 hours	SST	N	Y (venous & capillary)
Free T3	FT3	24 hours	SST	N	Y (venous & capillary)
Free Thyroxine (FT4)	FT4	24 hours	SST	N	Y (venous & capillary)
Full Blood Count	FBCX	24 hours	EDTA	N	N
Gamma Glutamyl Transferase (GGT)	GGT	24 hours	SST	N	Y (venous & capillary)
Gastric Parietal Autoantibodies	GASP	5 days	SST	Y	N
Globulin	GLOB	24 hours	SST	N	Y (venous & capillary)
Glucose	RBG	24 hours	Oxalate	N	Y (venous only)
Estimated Glomerular Filtration Rate (eGFR)	GFR	24 hours	SST	N	Y (venous & capillary)
HbA1C	GHBI	24 hours	EDTA / Lithium Heparin	N	Y (venous & capillary)
H. pylori Antigen (Stool)	HPAG	7 days	RF	Y	N
H. pylori Antibodies (IgG)	HBPA	5 days	SST	Y	N
HDL Cholesterol	HDL	24 hours	SST / Lithium Heparin	N	Y (venous & capillary)
Hepatitis A Antibodies IgG/IgM	HEPA	5 Days	SST	Y	N
Hepatitis B Core Antibodies (IgG/IgM)	HBC	24 hours	SST	N	Y (venous only)
Anti-HBe	HBEAB	5 Days	SST	Y	N
Hepatitis B DNA (Viral load)	DNAB	7 days	EDTA	Y	N
Anti-HBs (Hep B Surface Antibodies)	AHBS	24 hours	SST	N	(accredited under Flexible Scope for venous only)

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Test	Test Code	TAT	Sample Type/ Specific Requirements	Referral Test (Y/N)	ISO 15189 Accredited test* (Y/N)
Hepatitis B surface Ag (HBsAg)	AUAG	24 hours	SST	N	Y (venous only)
Hepatitis C Antibodies	HEPC	24 hours	SST	N	Y (venous only)
Anti HBc (IgM)	HBCM	5 days	SST	Y	N
Hepatitis A Immunity (IgG)	HAIM	5 days	SST	Y	N
Hepatitis C Core Antigen	HCAG	5 days	SST	Y	N
Hepatitis C Viral Load (PCR)	QPCR	10 days	SST	Y	N
HIV 1 & 2/p24Ag	HDUO	24 hours	SST	N	Y (venous only)
HIV PCR	RHIV	5 days	EDTA	Y	N
Hbe Ag	HBEAG	5 days	SST	Y	N
Homocysteine	HOMO	5 days	SST [17]	Y	N
HTLV 1&2 Abs. (Human T Lymphotropic Virus Type I-II)	HTLV	5 days	SST	Y	N
Immunoglobulin A	IGA	5 days	SST	Y	N
Immunoglobulin G	IGG	5 days	SST	Y	N
Immunoglobulin M	IGM	5 days	SST	Y	N
Intrinsic Factor Antibodies	IFAB	5 days	SST	Y	N
Insulin	INSU	24 hours	SST (Spun)	N	N
Iron	FE	24 hours	SST	N	Y (venous & capillary)
Iron Binding Capacity (Total)	TIBC	24 hours	SST	N	Y (venous & capillary)
Iron Binding Capacity (unsaturated)	UIBC	24 hours	SST	N	Y (venous & capillary)
Lactate Dehydrogenase (LDH)	LDH	24 hours	SST	N	Y (venous only)
LDL Cholesterol	LDL	24 hours	SST	N	Y (venous & capillary)
Lipoprotein (a)	LPOA	24 hours	SST	N	Y (venous & capillary)
Luteinising Hormone (LH)	LH	24 hours	SST	N	Y (venous & capillary)
Magnesium	MG	24 hours	SST	N	Y (venous only)
Malarial Parasites	MALP	10 Days	EDTA [4, 9, 14]	Y	N
Measles Antibodies (IgG) Immunity	MEAS	3 days	SST	N	Y (venous only)
MRSA SWAB - GROIN	MRSAG	5 Days	Blue Micro Swab	Y	N
MRSA SWAB - NOSE	MRSAN	5 Days	Blue Micro Swab	Y	N
Mumps Antibodies (IgG)	MUMP	3 days	SST	N	Y (venous only)
Non-HDL Cholesterol	NHDL	24 hours	SST	N	Y (venous & capillary)
Omega 3 Index - Basic	OMG3	14 Days	EDTA	Y	N
Omega Plus Profile	OMG+	14 Days	EDTA	Y	N
Parathyroid Hormone (Whole)	PTH	5 days	SST [4]	Y	N
Phosphate	PHOS	5 Days	SST (Spun)	Y	N
Potassium	K	24 hours	SST (Spun)	N	Y (venous only)
Progesterone	PROG	24 hours	Serum [10]	N	Y (venous & capillary)
Prolactin	PROL	24 hours	SST	N	Y (venous & capillary)

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Test	Test Code	TAT	Sample Type/ Specific Requirements	Referral Test (Y/N)	ISO 15189 Accredited test* (Y/N)
Prostate Specific Ag (Total)	PSPA	24 hours	SST	N	Y (venous & capillary)
Prostate Specific Ag (Free)	PSAF	5 days	SST	Y	N
Protein Total	PROT	24 hours	SST	N	Y (venous & capillary)
TB Quantiferon®-TB Gold	TBQ	5 days	X [1, 8]	N	N
Reverse T3	RT3	20 days	SST [27]	Y	N
Rheumatoid Factor	RF	5 Days	SST	Y	N
Rubella Antibody (IgG)	RUBE	24 hours	SST	N	Y (venous only)
S100 Malignant Melanoma	S100	7 days	SST	Y	N
Saliva Cotinine	SALCOT	7 days	Saliva Collection Tube/Container	Y	N
Selenium (Serum)	SELE	6 days	SST	Y	N
Cotinine (Serum)	SCOT	6 days	SST	Y	N
Serum Protein Electrophoresis	SELEC	6 days	SST	Y	N
Serum Zinc	ZINC	24 hours	Sodium Heparin	N	N
Sex Hormone Binding Globulin	SHBG	24 hours	SST	N	Y (venous & capillary)
Sodium	NA	24 hours	SST	N	Y (venous only)
Syphilis IgG/IgM	SERJ	5 days	SST	Y	N
Testosterone	TEST	24 hours	SST	N	Y (venous & capillary)
Free Testosterone	FTEST	24 hours	SST	N	Y (venous & capillary)
Transferrin Saturation	FESA	24 hours	SST	N	Y (venous & capillary)
Thyroglobulin Antibodies	TGAB	24 hours	SST	N	Y (venous & capillary)
Thyroid Peroxidase Antibodies	TPEX	24 hours	SST	N	Y (venous & capillary)
Thyroid Stim. Hormone	TSH	24 hours	SST	N	Y (venous & capillary)
Tissue Transglutaminase	TAA	5 days	SST	Y	N
Total Vitamin B12	TB12	24 hours	SST	N	Y (venous & capillary)
Triglycerides	TRI	24 hours	SST Lithium Heparin	N	Y (venous & capillary)
Total Thyroxine (T4)	T4	24 hours	SST	N	Y (venous & capillary)
TSH-Receptor Antibodies	TSI	6 days	SST	Y	N
Urate (Uric Acid)	UA	24 hours	SST	N	Y (venous & capillary)
Urine Microscopy	UMIC	1-7 days	RU	N	N
Urine Culture & Sensitivity	Cult	7 days	RU	Y	N
Urea	UREA	24 hours	SST	N	Y (venous & capillary)
Varicella Zoster Antibodies (IgG)	VZOS	3 days	SST	N	Y (venous only)
Vitamin A (Retinol)	VITA	7 days	SST	Y	N
Vitamin D (25-OH)	VITD	24 hours	SST	N	Y (venous & capillary)
Zika Antibodies IgG/IgM	ZKAD	7 days	SST	Y	N
Zika PCR - urine	ZIKU	9 days	RU	Y	N

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