PATHOLOGY
USER GUIDE



CONTENTS

1 INTRODUCTION

Efficient and appropriate use of the Laboratory Service is central to the modern practice of medicine. The aim of this handbook is to provide clear guidance on how and when to use our Laboratory Service, which analyses are available, and which sample type should be used. We process more than 200,000 individual pathology tests each year. Analyses are performed using the latest technologies by qualified scientific staff assisted by trained support staff. All processes undergo rigorous quality control and the Laboratory participates in external quality assessment programmes. Due to unforeseen circumstances has temporarily voluntarily suspended its UKAS accredited for ISO standard 15189: 2022. The suspension will end in February 2026 Although the Pathology Department is temporarily suspended, the very high level of quality is maintained.

Clearly, a concise handbook cannot give comprehensive coverage of all aspects of the service we offer. Contact names and telephone numbers of key senior members of staff are given – please contact us whenever you have a query over which investigation is most appropriate, what collection conditions might affect your result and how you should interpret that result. Clinical advice is available from appropriate consultants and is an essential part of the service we offer: effective liaison with us improves our service to you.

We have made every effort to ensure that the information in this handbook is correct at the time of publication. However, information will change as new technologies become available and the service evolves to meet the needs of our users. We welcome any comments or suggestions you would like to make, positive or negative, so that these can be incorporated in future editions of the handbook.

Pathology puts patient's health and Safety first and all processes have a risk assessment performed to reduce any risks that may occur through patient's care pathway regarding Pathology.

This user guide is designed to help you get the most from the Pathology Services available at KIMS Hospital.

KIMS Pathology has a duty of care to patients and other Pathology users. If there are any changes to agreements due to changes in laboratory activities which may affect the examination results, Pathology must communicate this to the users.

As an independent hospital, all requests are governed by the Clinicians with KIMS Hospital Practicing Privileges unless Pathology cannot provide a particular test. This will be communicated to the Clinical teams.

Requests are consultant driven and no tests can be requested by patients. Pathology staff will be empowered to challenge some requests depending on their clinical relevance & the number of sample tubes taken per patient.

Patient's Consent

A patient must give consent to have samples or specimen taken. By allowing this, the patient has given their consent. The samples or specimens with the accompanying request form is a given

that the laboratory can continue to process any tests that are requested on the request form by a clinician or clinical area. For further information regarding patient's consent, refer to **CMA-POL-07: Consent to investigations and Treatment**

Right patient, first time.
To reduce patients' harm when it comes to taking samples and specimens-Get it right first time: *GIRFT*

Department Overview and Current Context

The Pathology Laboratory Service, which operates within KIMS Hospital provides a diagnostic laboratory service offered from 08:00–17:00, 5 days a week; and will provide an 08:00–13:00 service on Saturdays and Sundays **on request**. The Laboratory Service is supported by Biomedical and Assistant Healthcare Scientists.

Due to unforeseen circumstance beyond the laboratories control the Laboratory No. 21162 UKAS ISO 15189 accreditation has be voluntarily temporally suspended compliance.

2 PATHOLOGY LABORATORY LOCATION

The Pathology laboratory is located on the lower ground floor of the Kent building of KIMS hospital main site

Laboratory opening hours

The laboratory is operational 08:00–17:00, Monday–Friday and will provide an 08:00–13:00 service on Saturdays and Sundays **on request**.

Out of routine working hours the Pathology Service Manager/ Lead BMS may be contacted via the KIMS Hospital Switchboard. Pathology have an On-call Rota, details available on the S-Drive.

Weekends

At weekends the Laboratory is open for acceptance of samples for analysis up to 12 Mid-day and is staffed by a single Biomedical Scientist.

Bank Holidays

The Laboratory is open as required by KIMS Hospital on Bank Holidays, this is agreed with the clinical teams prior to the event. The Laboratory will be covered by a single Biomedical Scientist.

Out of Hours

Out of hours an on call Biomedical scientist is available via switchboard for urgent queries or concerns.

3 CONTACT NUMBERS AND KEY PERSONNEL

KIMS Hospital main Switchboard:.....01622 237500/x2

Pathology Extension Numbers:

Microbiology: x7684
Main Pathology Reception: x7694/7690
Blood Sciences: x7696

Contact Names and Telephone Numbers:

Pathology Manager: Colin Brisley x8228
Lead Biomedical Scientist & Pathology Quality Manager:
Andrea Ferrige.....x8190

Pathology Clinical Director (and Haematology Consultant):
Dr Maadh Aldouri: .....Via Switchboard

For clinical advice and interpretation contact (all via KIMS Hospital Main Switchboard):

Consultant Clinical Scientist: Edward Kearney
Haematology Consultants: Maadh Aldouri, Lalita Banerjee, Saad Rassam
Microbiology Consultant: Srinivasulu Reddy

4 CLINICAL INFORMATION

It is particularly helpful to us to receive as much clinical information as possible on the laboratory request form as this ensures that the appropriate diagnostic tests are performed on your behalf.

5 CLINICAL ADVICE AND INTERPRETATION

Clinical advice and interpretation are available on request via the Pathology Service Manager who will advise regarding contacting the Consultants for further advice. Clinical and interpretative comments are also added to the results if indicated. Out of hours clinical advice is available by contacting the on-call Haematologist, or Consultant Microbiologist via KIMS Hospital Main Switchboard. The is no Clinical advice given Out of hours by the Consultant Clinical Scientist.

All laboratory advice and interpretation are readily available and these must meet the needs of both patients and users alike.

6 SPECIMEN AND REQUEST FORM LABELLING

Please help us to help you by completing request forms legibly with all the necessary information. **It is essential** that the patient details are clear and accurate and also that we have a clear indication of the destination for the report and the requestor.

Specimens and request forms must be completed in accordance with the Pathology Specimen Acceptance Policy HOP-POL-20. Blood transfusion samples must be hand written on the specimen including the signature of the person taking the sample.

Requests for investigations must include the following information:

- Patient demographic details including KIMS Hospital Number.
- Date and time of collection of specimens.
- Requesting doctor/clinician/nurse.
- Return destination for the report.
- Relevant clinical details including current treatment.
  Please provide as much information as possible, including anticoagulant drugs or other medication.
- Tests required.

Correct Samples for Blood Transfusion

NOTE: All samples for Blood Transfusion analysis **MUST** be fully labelled with patient's surname and forename(s), date of birth (not age), patient's hospital number and the location at which the patient currently resides. This information must be hand written (by the person drawing the blood **only**) and the label signed and dated. All patient details must be correct and thoroughly checked.

Any samples not meeting current guidelines as shown in the Pathology Specimen and Request Form Acceptance Policy will not be processed. Communication of why a request has been rejected will be given to the Clinical Team. Patients may be called by the clinical area if required. Only "Precious Samples" will not be rejected. Those samples that cannot be repeated; including Histology and Bone Marrow requests.

This may result in delay of provision of blood or pathology results for your patient. Section 7 (below) details specimen request requirements.

To minimise the risk of incorrect labelling of samples and recalling of the patient. "Pause & Check" what you are doing.

7 SAMPLE REQUIREMENTS – INCLUDING VOLUMES AND PROFILES

All samples should be transported promptly to the laboratory, at room temperature (except where specified) and away from direct sunlight. Appropriate blue transport boxes should be used for this purpose and the samples should be placed inside individual sample bags. These

boxes must be wiped clean on a regular basis to prevent contamination and reduce health issue. Use a hospital disinfectant.

If specimens require urgent processing, please write "URGENT" conspicuously on the request form (AND tick the appropriate box) & contact the laboratory to inform them that it will be coming.

The Laboratory offers several test profiles. The basic constituent tests are:

- Full Blood Count (FBC): all blood parameters (check the types and numbers of cells in blood sample).
- Urea & Electrolytes (U&E): Sodium, Potassium, Creatinine, Urea, Chloride, eGFR.
- Liver function test (LFT): Total Bilirubin, Total Protein, Albumin, Alanine Transaminase, Alkaline Phosphatase, Aspartate Transaminase.
- Lipid profile: Total Cholesterol, HDL-Cholesterol, LDL-Cholesterol, Triglyceride, Cholesterol: HDL Ratio, Non-HDL: Cholesterol Ratio.
- Thyroid function test (TFT): Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), Free Thyroxine (FT3)
- Bone Profile (Bone): Calcium, Adjusted Calcium, Phosphate, Albumin, Alkaline Phosphatase, Total Protein
- Coagulation Screen: APPT, PT INR. FIB
- HbA1c

No other profiles are in use – please always specify in other cases exactly which tests you require. The laboratory will always undertake to do as many of the requested analyses as possible on the sample provided. In general, all of the above tests can be done upon receipt of an appropriate sample including a single filled, EDTA, 4ml gel separator tube, or correctly-filled Blue Top container. Some more specialised tests, in particular those which we refer to regional centres, may require larger sample volumes or additional tubes. Please contact the laboratory to discuss sample requirements for specialised tests.

Urine samples for microbiology: Urine samples for microbiology should be collected into a sterile universal container, > 1 ml and no more than the maximum fill line. The sample should be labelled with name, DOB, hospital number and date and time taken. Patient collection leaflet available on Q-Pulse (HOP-FOR-65)

(NB: Due to the quickness of processing urines for culture & microscopy from receipt into the laboratory Boric acid red topped universals will not be introduced to KIMS Hospital. If there is a delay in processing, the urine container will be placed in the fridge to prevent growth of further organisms. Turnaround times from urine sample being taken to processing in the laboratory must be within 4 hours if unrefrigerated.

Also, Boric acid could cause false negative culture if urine is not filled to the correct mark on the specimen container. Boric acid may be inhibitory to some organisms, so should not be used for urine dipstick tests).

Faecal samples for Microbiology: Faecal specimens should be submitted to the laboratory in an appropriate plain screw capped CE leak proof specimen container (Blue top stool sample pots) as soon as possible after collection. Submit a sample that fills at least a third of the container if possible, but please do not overfill the container. Sample should be labelled with name, DOB, hospital number and date and time taken. Patient collection leaflet available on Q-Pulse (HOP-FOR-66)

MRSA Samples: Samples are collected as per IPC-POL-12: MRSA Screening Policy and ICP-FOR-07 MRSA Screening tool

Swab samples other than MRSA: Clinical areas use the Marsden Manual and further information is regarding technique on how to taken a wound is available in the Wound Policy written by the Out-Patient's Department.

All documents are available via Q-Pulse or on request from Pathology

Table 1: Sample Containers

	Container	Minimum Volume	Comments
Haematology			
FBC	Purple top (EDTA)	1ml	All samples must be processed within **24 hours** from collection. Samples should be stored at 4–22°C and away from direct sunlight.
ESR	Purple Top (EDTA)	4ml	Samples must be tested within **24 hours**
Blood Transfusion			
Group and Save	Pink Top	7ml	All samples must be processed within **24 hours** from collection. Samples should be stored at 4–22°C and away from direct sunlight.

	Container	Minimum Volume	Comments
Crossmatch	Pink Top	7ml	All samples must be processed within **24 hours** from collection. Samples should be stored at 4–22°C and away from direct sunlight.
Coagulation			
Coagulation screen INR	Blue Top	Must be filled to line (see Fig. 1 below)	All samples for coagulation must be processed within **4 hours** of collection.
Biochemistry			
U&E	Gold Top	5ml	All samples must be processed within **24 hours** from collection. Samples should be stored at 4–22°C and away from direct sunlight.
LFT	Gold Top	5ml	As above.
Lipid Profile	Gold Top	5ml	As above.
TFT	Gold Top	5ml	As above.
Bone	Gold Top	5ml	As above.
Ferritin	Gold Top	5ml	As above.
Uric Acid	Gold Top	5ml	As above.
GGT	Gold Top	5ml	As above.
Magnesium	Gold Top	5ml	As above.
Albumin	Gold Top	5ml	As above.
Phosphate	Gold Top	5ml	As Above

	Container	Minimum Volume	Comments
Amylase	Gold Top	5ml	As above.
Iron	Gold Top	5ml	As above.
CRP	Gold Top	5ml	As above.
Glucose	Gold Top	5ml	As above.
T. Protein	Gold Top	5ml	As above.
CEA	Gold Top	5ml	As above.
T.PSA	Gold Top	5ml	As above.
Vitamin D	Gold Top	5ml	As above.
TNT	Gold Top	5ml	As above.
HbA1c	Purple Top (EDTA)	4ml	Send to the lab as soon as possible although stable for 24 hours at 4oC. Do not centrifuge
Microbiology			
Urine Culture*	White Top Universal	>1ml	Samples should be stored at 4–8°C.
Culture swab/ MRSA screen*	Blue Top swab	N/A	Samples should be stored at 4–8°C.
Viral swab	RNA/DNA shield swab	N/A	Samples should be stored at room temperature.
Histology			
Sample for histology	Container with formalin	N/A	Samples should be stored at room temperature.

*All microbiology samples should be processed within 24 hours of collection and delivered to the laboratory as soon as possible after collection (within 24hrs). The laboratory will advise you on the suitability of the sample for performing additional tests.

Blood samples requiring centrifugation must be received within the laboratory within 4 hrs of draw, unless centrifuged at source

For specialist tests please discuss with the Laboratory directly.

Results may be affected by factors such as **lipaemia, icteric** or **haemolysis**. Tests will be rejected if the samples are clotted, insufficient and haemolysed. These are a result of bad technique. Haemolysis can also be caused due to patients veins as they may be difficult to bled. The laboratory will advise you regarding this.

Additional investigations may be requested by telephoning the laboratory. Tests may be added to samples within 48 hours of receipt of the sample, an updated request form **must** also be submitted to the laboratory of any additional tests requested. All coagulation tests must be performed within 4 hours of taking the sample.

Figure 1: Fill Level for Coagulation Tubes

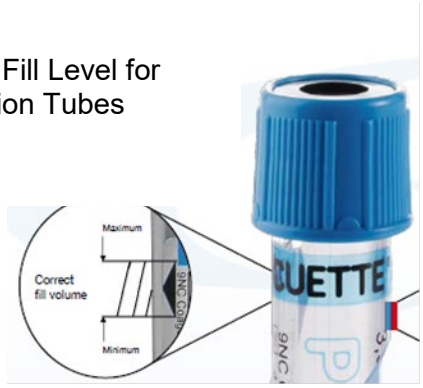

Figure 1: Fill Level for Coagulation Tubes

NB: It has been observed that when collecting coagulation tubes as the first sample using the butterfly needle collection system, the tubes may not always fill to the minimum line causing them to be rejected by the Laboratory. If you experience any problems collecting or filling coagulation tubes then please contact the Laboratory to discuss.

Ensure the correct order of draw is done to stop contamination from other anticoagulants which may affect patients results.
First take a white tube when a light blue citrate sample for coagulation studies is required. Discard the white tube to prevent the light blue citrate sample being either insufficient or a clotted. If this occurs the sample will be rejected and a repeat will be required.

Tube guide, order of draw and Tests performed at KIMS Pathology

NOTE: If you have referral tests, please make sure that you have checked TDL book for any another special requirement. Always take an extra tube for all referral tests.

Order of draw and required volume	Cup colour	Additive	Tests	Special Instructions	Required Bottles / Inverts
1	 WHITE	None	Discard Tube	Used if  is taken to prevent insuficent crite samples.	N/A
2 3.5 ml	Light BLUE 	Sodium Citrate	Coagulation Screen INR	The bottle must be filled to the line marked around its edge for accurate results. Sample is stable 4 hours only and needs to reach the lab ASAP no later than 15:00 as per list provided. Not to be left over night at SMC.	1 
3 5 ml	 GOLD	SST	UE, LFT, GLUCOSE, Lipid Profile, Bone Profile, TFT, PSA, CRP, Magnesium, Fe/Iron, Ferritin, CEA	In house tests can be managed with one 5 ml SST tube. Additional tubes for referral tests are mandatory.	1 
4 4 ml	 PURPLE	EDTA	FBC, ESR, Blood film, HbA1c (HbA1c is a referral test)	If only FBC, ESR and blood film – one 4 ml tube, if HbA1c requested as well, take another tube.	1 or 2 
5 6 ml	 PINK	EDTA	Group and save, Crossmatch (Referral tests)	Samples must be hand written and 30 minutes apart if no history.	2 
6 6 ml	 Dark Blue	Sodium Citrate	Trace Elements	TDL referral tests	1 

8 TURNAROUND TIMES

Table 2: Standard Test Turnaround Times (TATs)

Test	TAT	Location Analysed[1] (if not at KIMS Hospital)	Comments
All urgent samples	Within 1 hour of receipt		
All ward samples	Within 2 hours of receipt		Grossly abnormal results will be phoned as soon as possible.
FBC	24 hours		
ESR	24 hours		
U&E	24 hours		
LFT	24 hours		
Lipid Profile	24 hours		
TFT	24 hours		If received in the laboratory after 16:00 to be tested Monday Morning
Bone	24 hours		
GGT	24 hours		
GLU	24 hours		
IRON	24 hours		
VITD	24 hours		

[1] See Table 9 for External Laboratory Details

Test	TAT	Location Analysed[1] (if not at KIMS Hospital)	Comments
MG	24 hours		
CEA	24 hours		If received in the laboratory after 16:00 to be tested Monday Morning
T. PROTEIN	24 hours		
PSA	24 hours		If received in the laboratory after 16:00 to be tested Monday Morning
FER	24 hours		If received in the laboratory after 16:00 to be tested Monday Morning
CRP	24 hours		
TNT	Within 2 hours of receipt		If received in the laboratory on Saturday mornings, TNT will be referred to MTW- Biochemistry Department for testing
URIC ACID	24 hours		
COAGULATION	4 hours		
HbA1c	24 hours		
MRSA SCREEN	24 hours		
WOUND SWAB	48–72 hours		
GYNAE SWABS	48–72 hours		
URINE CULTURE	24–48 hours		
TISSUE/ FLUID FOR CULTURE	48–72hours	MTW	
HISTOLOGY	Refer to MTW	MTW	Contact KIMS Hospital Pathology Department directly for TATs.
Referral laboratory results	As per referral lab published TAT	TDL, MTW, KCH (SE-HMDS)	Published turnaround times available on request

Once results are finalised they will be available on Compucare and available for viewing by the requesting clinician(s) in charge of the patient.

If you require more urgent results please discuss your requirements with the Pathology Service Manager.

9 SPECIALIST INVESTIGATIONS

Any specialist tests requested will be sent to the appropriate referral laboratory.

10 BLOOD TRANSFUSION SERVICE SPECIFIC

MTW-Blood Transfusion department process and issue blood components for KIMS Hospital.

It is extremely important that the patient is correctly identified at the time of blood sampling. This is the responsibility of the person collecting the blood. Samples should be correctly labelled (see Sections 6 & 7) in the presence of the patient and confirmed by the patient. The labelling of tubes MUST NOT be delegated to a third party.

Please remember: BLOOD CAN KILL

Components issued by the Pathology Laboratory

- Crossmatched blood.
- Emergency group O (D) Negative blood.
- Fresh frozen plasma.
- Platelets.
- Cryoprecipitate.
- Major haemorrhage units as part of the Code Red procedure.

For full details refer to the Blood Transfusion Policy (PAT-POL-02).

Special requirements: If your patient has special requirements please discuss these with the Pathology Service Manager or Lead BMS when requesting blood components. If you are in any doubt regarding a patient's requirements please refer to the appropriate guidelines or discuss with a Haematology Consultant.

ALWAYS TELEPHONE THE LABORATORY FOR URGENT BLOOD

Table 3: Blood Transfusion Turnaround Times

Test	TAT	Comment
Routine Crossmatch	24 hours	
Emergency Crossmatch	2 hours	From receipt of request and sample at referral laboratory.
Urgent group compatible un-crossmatched	2 hours	From receipt of request and sample.
O negative (flying squad)	Immediately available	
FFP	Code Red request only	From receipt of request.
Platelets	Code Red request only	From receipt of request.

The provision of compatible crossmatched blood may be delayed where **atypical auto** or **allo antibodies** are detected in the patient's blood.

You will be informed if this occurs and additional samples may be requested for further analysis.

For routine blood crossmatching and the provision of non-urgent blood components please give the laboratory **at least 24 hours' notice**.

When requesting group and save or crossmatch of blood for patients going to theatre please refer to the standard blood ordering schedule (MSBOS). **PAT-INF-06**

11 URGENT REQUESTS

- Please request tests to be performed urgently only when it is clinically essential.
- All of our work is processed rapidly and the results are available in a timely manner. The agreed turnaround times for each test are published within this user guide.
- If you wish for a sample to be analysed urgently, please make sure that the request form clearly states this and always contact the laboratory to discuss.
- These samples will be handled separately and the results telephoned to the requesting doctor/clinician/nurse as soon as possible if applicable.

12 RESULT DELIVERY: TELEPHONED AND EMAILING RESULTS

- Please avoid asking us to telephone results if possible as this interferes with the work of the Laboratory.
- Significantly abnormal results will be telephoned to the ward and/or requesting clinician.
- The Pathology Laboratory Service has an agreed list of critical/alert results that will always be telephoned to the ward and/or requesting clinician (see Table 4 below).

Table 4: Telephone and Emailing Alert Ranges

Analyte	Units	Action limits		Comments
		Lower	Upper	
BIOCHEMISTRY				
Renal function				
Sodium	mmol/L	≤120	≥160	≤130 <16 yrs
Potassium	mmol/L	≤3.0	≥6.0	
Urea	mmol/L	30.0		≥ 10 if < 16 yrs
Creatinine	umol/L	354		≥200 <16 yrs
Liver Function				
ALT – Alanine transaminase	U/L	15xULN		N.10-50 M; 10-35 F
AST – Aspartate transaminase	U/L	15xULN		N. 0-40 M; 0-32 F
Amylase	U/L	≥500		
Calcium (adjusted)	mmol/L	1.8	3.2	
CRP	mg/L	-	300	
Glucose (diabetic)	mmol/L	2.5	30	
Glucose ≥16 yrs	mmol/L	2.5	25	
Glucose <16 yrs	mmol/L	2.5	≥15	
Magnesium	mmol/L	0.4	-	
Phosphate	mmol/L	≤0.3	n/a	
TSH	mIU/L	<0.27	30	Only email results if not on thyroid treatment.
FT3	pmol/L	-	10	
FT4	pmol/L	-	35	
Troponin	ng/L	-	>14.0	
HbA1c	mmol/mol	20	42	Any extra peaks identified, specimen must be referred to TDL to confirm a possible Hb Variant.
Urate/ Uric acid	Umol/L	≥340		Only in pregnancy
HEAMATOLOGY				
Hb – Haemoglobin	g/L	<70		Microcytic/ macrocytic anaemia
	g/L	<80		Normochromic, normocytic, may suggest blood loss or bone marrow failure.
	g/L	>160 F >180 M		Or haematocrit. Above 55 I/I. Only requires urgent referral if compounding medical problems.
White Cell Count				
Neutrophils	$X10^9/L$	<1.5	>20	Unless post op.

Analyte	Units	Action limits		Comments
		Lower	Upper	
Lymphocytes	$X10^9/L$	>50		Requires urgent but not immediate referral.
Platelets	$X10^9/L$	<30		
	$X10^9/L$	>600		Requires assessment and referral.
	$X10^9/L$	>1000		Requires urgent referral for assessment.
INR		>4.9		
Fibrinogen	g/L	≤ 1.5		

Microbiology Critical communication list

- All positive results to be emailed to the clinical teams below

Microbiology Tests	Units	Action limits	Comments
MRSA Swabs	NA	Positive	○ Inform IPC, Microbiology Consultant, Requesting Clinician, RMO & Lead BMS. ○ Both In-house and referred tests
Wound Swabs	NA	Positive	
Urines	NA	Positive	
All other Microbiology	NA	Significant results	
Blood Cultures	NA	Positive	○ As above ○ Telephone ward if patient is an inpatient
C. Diff	NA	Positive	

- We will always ask you to confirm any results that we do give you by telephone by reading the results back to us.
- We will always ask for the name of the person taking the results for audit purposes.
- The above protocol will also be applied if you telephone the Laboratory for results.

13 HIGH RISK SAMPLES

The Laboratory operates a policy of universal safety precautions for all samples and we recommend that you regard all blood as being potentially infectious. High risk labelling of samples is **not required**.

14 MEASUREMENT UNCERTAINTY AND FACTORS AFFECTING COAGULATION RESULTS

The calculation of the Measurement Uncertainty (MU) is undertaken by the laboratory service through review and update at regular intervals. Information in relation to the MU for the laboratory tests carried out within the Pathology Department can be obtained by contacting a member of the Pathology Team.

14.1 Pre-Examination Factors Affecting Pathology Results

All results will be subject to variability arising from how the sample is collected and stored. Differences in patient preparation, specimen collection technique, time of sampling, transportation, storage time and preparation of the primary sample may all alter the results and the measurable amount of an analyte in a sample. Other factors that may influence pathology results are generally patient specific and include stress, underlying clinical conditions and certain drug therapies.

As users of the Pathology Laboratory Service, you play a key role in reducing the effects of pre-analytical variables on results by following the information and advice provided in this Users Guide to ensure that you collect a good quality sample at the appropriate time and for the appropriate tests. There are a number of steps that you can take to ensure the quality & integrity of the sample that you send to us:

- Always check the individual sample requirements.
- Ensure the samples are taken in the correct order of draw:
    1. Blood culture or no additive tubes,
    2. Coagulation tubes,
    3. Serum tubes with/without gel,
    4. Heparin tubes with/without gel,
    5. EDTA tubes,
    6. Glucose tubes, and
    7. Other tubes
- Do not take the sample from an arm with a drip.
- Do not tip blood from one bottle to another, as this may contaminate the sample with an inappropriate anticoagulant.
- Samples must be filled exactly to the level indicated on the bottle (see Figure 1).
- Overfilled and under filled samples may be unsuitable for analysis.
- As soon as the sample is in the bottle, mix thoroughly by gentle inversion between 8 -10 times to prevent the samples clotting; **do not shake**.
- Ensure the samples are delivered promptly to the Laboratory.

14.2 Examination Factors Affecting Pathology Results

As with all examination procedures there are numerous analytical factors that may introduce variability into the results of our Pathology tests. These include uncertainty of the calibrator value and dispensed volumes, reagent and calibrator batch variations, equipment maintenance and age, different operators, and environmental fluctuations. There may also be substances present in the sample that interfere with the test procedure such as certain drugs, biotin or bilirubin. The Laboratory pays careful attention to these factors and takes a range of steps to minimise their effects on results including:

- Where available, all tests are referenced to and calibrated against a known reference material or accepted standard.
- Following national guidelines and protocols where available.

- Annual or 6 monthly service and calibration of analysers and appliances across Pathology and off-site including Fridges, freezers and incubators.
- Bi-Annual commercial service and calibration of all laboratory pipettes
- Annual commercial service and calibration of the laboratory balance
- A comprehensive internal and external quality control programme with careful monitoring of the accuracy, precision and bias of all assays and tests where appropriate.
- Strict adherence to standard operating procedures and manufacturer's maintenance schedules.
- Regular competency assessment of all staff.
- Assessing the limitations, interfering substances and cross reactions affecting all assays.

14.3 Post-Examination Factors Affecting Haematology & Transfusion Results

A number of factors can affect the interpretation of test results. Some assays/tests produce raw numerical data that is then manipulated to produce a final result, and it is possible for calculations to introduce errors (e.g. rounding up numbers) and lead to variability of results. Disease and physiological factors such as biological variation, stress and chronic illness can all bring uncertainty to the interpretation of results. If the result is distinct from the clinical decision value then these factors are generally of little or no importance but as results approach clinical decision values they may significantly affect interpretation.

Automated analysers function within operating limits of accuracy and precision. This may produce slight variance in results if a sample is analysed more than once. These limits are generally very small and the resulting changes in results are not clinically significant. Common accuracy and precision values for our analysers are given in Tables 5–8 below.

Table 5: Accuracy within FBC Parameters

Parameter	Accuracy
WBC	Within ± 3.0% or within ± 0.20 x 10^3 / µL
RBC	Within ± 2.0% or within ± 0.03 x 10^6 / µL
PLT	Within ± 5.0% or within ± 10.0 x 10^6 / µL
Neut%	Coefficient correlation r ≥ 0.90
Lymph%	Coefficient correlation r ≥ 0.90
Mono%	Coefficient correlation r ≥ 0.75
Eos%	Coefficient correlation r ≥ 0.80
Baso%	Coefficient correlation r ≥ 0.50
Neut#	Within ±3.0% Neut%
Lymph#	Within ±3.0% Lymph%
Mono#	Within ±2.0% Mono%
Eos#	Within ±1.0% Eos%

Parameter	Accuracy
Baso#	Within ±1.0% Baso%

Table 6: Precision within FBC Parameters

Parameter	Precision
WBC	CV 3.0% or less (when WBC ≥ 4.0 x 10^3 / µL)
RBC	CV 1.5% or less (when RBC ≥ 4.0 x 10^6 / µL)
Hb	CV 1.5% or less
HCT	CV 1.5% or less
MCV	CV 1.0% or less
MCH	CV 2.0% or less
MCHC	CV 2.0% or less
PLT	CV 4.0% (when PLT ≥ 100 x 10^3 / µL)
Neut#	CV 8.0% or less
Lymph#	CV 8.0% or less
Mono#	CV 20.0% or less
Eos#	CV 25.0% or less
Baso#	CV 40.0% or less

Table 7: Coagulation

	Intra assay reproducibility CV %	Inter assay reproducibility CV %
PT INR	0.9	1.6
APTT	0.3	1.5
Thrombin Time	1.9	4.1

Precision

PT INR & APTT: The coefficient of variation of the analytical system (total CV) on the same lot of control plasma should be less than 5%.

Thrombin Time

The coefficient of variation of the analytical system (total CV) on the same lot of control plasma should be less than 10%.

Table 8: Biochemistry

Test	% CV Accuracy
Albumin	≤2%
ALP	≤2%
ALT	≤3%
Amylase	≤3%
AST	≤3%
Calcium	≤2%
Chloride	≤3%
Cholesterol	≤2%
Creatinine	≤3%
CRP	≤5%
Gamma GT	≤2%
Glucose	≤2%
HDL	≤3%
LDL (Assayed)	≤2%
Iron	≤2%
Magnesium	≤2%
Phosphate	≤2%
Potassium	≤2%
Sodium	≤2%
Total Bilirubin	≤3%
Total Protein	≤3%
Triglyceride	≤2%
Urate	≤2%
Urea	≤2%
Ferritin	≤4%
FT3	≤5%
FT4	≤5%
Total PSA	≤2%
HbA1c	≤1.7%
Troponin T	25– < 100 ng/l ≤ 5% > 100 ng/l ≤ 3%
TSH	0.1–4 mU/ml ≤5% 4-20 mU/ml ≤2%
Vitamin D	> 50 nmol/L ≤5.5%

Test	% CV Accuracy	
CEA	4.6 ng/ml	≤ 3%
	10–50 ng/ml	≤5%
	50–500 ng/ml	≤ 8%

Microbiology methods require manual interpretation.

14. 4 Manual Methods

Examples of manual methods include blood film reporting, microbiology culture, and urine culture and Erythrocyte Sedimentation Rate (ESR),

Manual intervention where needed, requires subjective decisions to be made by a Biomedical Scientist. This applies to all manual methods such as blood film reporting, MRSA screening, urine microscopy and ESRs. In these cases, the quality of results is maintained by competency assessment and participation in external quality assurance schemes. Standard Operating Procedures (SOPs) are followed for all procedures.

15 REPORTS

Results will be available to view on Compucare and WinPath Enterprise as soon as they have been authorised. Results that fall outside the normal reference range will be highlighted in bold and appropriate comments will be added.

Depending on severity of abnormal results, they will be either telephoned to the clinical requestor with a follow-up email or emailed to their secretary or requesting location. All calls are logged on various platforms within, Compucare, telephone logs & WinPath Enterprise (the Pathology's LIMS). When a result is emailed or called though, this is logged on to patient's note pad on Compucare as evidence, that the results have been communicated to clinical teams.

Only hardcopies of results will be sent out to the requesting area when Pathology interfaces/ IT systems are in downtime.

Reference ranges are periodically re-evaluated and can be found on the paper and electronic report alongside each result. If a reference range or test comment has been recently altered/added a comment will be placed below the test for a period of **six months** to indicate this and then removed.

Clinical Decision Limits are reviewed at regular intervals with input from the Lead Haematology Consultant, Clinical Scientist and where applicable the Microbiology Consultant.

16 EVALUATION

The laboratory will evaluate its service to ensure it meets the needs of both patients and users alike. Evaluation will be performed by performing audits and a Pathology User Survey. Processes to be evaluated are management, support and pre- examination, examination and post examination across Pathology.

There will be a review of requests, suitability of procedures and samples to ensure that these are appropriate for both patients and users alike. If there are any trends, issues or concerns including clinically appropriate and necessary, highlighted during these audits, these will be escalated to higher management, including the Laboratory Director and Medical Director.

17 SAMPLES REFERRED TO OTHER TRUSTS/LABORATORIES FOR ANALYSIS

There are a number of tests that are not cost effective to be performed in the Pathology Laboratory and these are referred to specialist laboratories outside of KIMS Hospital.

The KIMS Hospital Pathology Department ensures that each referral laboratory has full UKAS accreditation and where available participates in a recognised external quality control scheme, and this status is checked annually. Table 9 below lists the referral laboratories that we currently use, and which tests are analysed at each laboratory.

KIMS Hospital have Service Level Agreements (SLA) with:

- MTW- Pathology for the below specialities and out of hours for routine blood tests
- TDL for all other test repertoire
- DVH- Occupational Health requests

There is no SLA for KCH (SE-HMDS), but KIMS Hospital is invoiced for any Specialist Haematological requests performed there.

Table 9: External Pathology Laboratories used by KIMS Hospital

Test	Referral Laboratory	Hospital	Reference Lab TAT
Myeloma markers & haematology specialist tests including bone marrow	KCH (SE-HMDS)	KCH (SE-HMDS) Kings Healthcare NHS Trust Denmark Hill London SE5 9RS	5 Working days from receipt
Blood transfusion including provision of O neg emergency units	Haematology, Blood Transfusion Dept	**MTW** Maidstone Hospital Hermitage Lane Maidstone Kent ME16 9QQ	24 hours (2 hours urgent requests)
Histology	Histopathology laboratory	**MTW** Maidstone Hospital Hermitage Lane Maidstone Kent ME16 9QQ	10 working days

Test	Referral Laboratory	Hospital	Reference Lab TAT
Microbiology – Faeces, gynae samples, tissues and fluids for culture	Microbiology laboratory	**MTW** Maidstone Hospital Hermitage Lane Maidstone Kent ME16 9QQ	5 working days
Out of hours routine blood science tests	Blood sciences	**MTW** Maidstone Hospital Hermitage Lane Maidstone Kent ME16 9QQ	24 hours
Occupational Health Screening samples	Pathology Laboratory	DVH Darent Valley Hospital Darenth Wood Road Dartford DA2 8DA	N/A
All other referral tests	Blood sciences laboratory	**TDL** **The Doctors Laboratory** **1 Mabledon Place,** **London** **WC1 9AX**	Refer to The Doctors Laboratory (TDL) Guide.

18 TIME LIMITS FOR REQUESTING ADDITIONAL EXAMINATIONS

Due to the deterioration of samples, there is a time limit on requesting additional examinations. Therefore, 48hrs after the original sample was taken, we will be unable to add additional examinations to the sample as the integrity of the sample may have become compromised.

19 REFERENCE RANGES: LABORATORY NORMAL RANGES

The reference ranges which have been applied by the KIMS Hospital Pathology Laboratory's Blood Science Service for the reporting of requests are based upon the parameter reference ranges quoted in the following texts:

Lewis, S. M., Bain, B. J., Bates, I., Dacie, J. V., & Dacie, J. V. (2006). *Dacie and Lewis practical haematology*. Philadelphia: Churchill Livingstone/Elsevier.

IM Appel , B Grimminck *et al.* Journal of Thrombosis and Haemostasis 2012;10:2254–2263.

P Toulon, M Berruyer *et al.* Thrombosis and Haemostasis 2016;116:9-16.

Pathology Harmonisation, Manufacturer references.

Reference ranges are reviewed at regular intervals according to local laboratory standard operating procedures.

Reference ranges are given in Table 10 below.

Table 10: Reference Ranges

Biochemistry

Test	Units	Adult Reference Ranges						Ref Range derived from
	Gender	Not stated		M		F		
Albumin	g/L	35	50					Pathology Harmonisation
ALP	U/L	30	130					Pathology Harmonisation
ALT	U/L			10	50	10	35	Roche
Amylase	U/L	28	100					Roche
AST	U/L			0	40	0	32	Roche
Calcium	mmol/L	2.2	2.6					Pathology Harmonisation
A. Calcium	mmol/L	2.2	2.6					Pathology Harmonisation
CEA	ug/L		5					Roche <5 (non-smokers) <10 (smokers)
Cholesterol	mmol/L	<5.0						Desirable
Chloride	mmol/L	95	108					Pathology Harmonisation
Creatinine	umol/L			62	106	44	80	Roche Jaffe
CRP	mg/L	0	5					Roche
Ferritin	ug/L			30	400	13	150	Roche
Ft3	pmol/L	3.1	6.8					Roche
Ft4	pmol/L	12.0	22.0					Roche
GGT	U/L			10	71	6	42	Roche
Glucose	mmol/L	3.5	5.4					Nice
HbA1c	mmol/mol	20	42					IFCC
HDL	mmol/L	>1.0						Desirable
Iron	umol/L	5.8	34.5					Roche
Potassium	mmol/L	3.5	5.3					Pathology Harmonisation
LDH	U/L	240	480					Roche
LDL	mmol/L	<3.0						Desirable
Magnesium	mmol/L	0.7	1.0					Pathology Harmonisation
Sodium	mmol/L	133	146					Pathology Harmonisation
Phosphate	mmol/L	0.8	1.5					Harmony
PSA	ng/mL	0	2.5		49 yrs.			Roche
PSA	ng/mL	0	3.0		59 yrs.			Roche
PSA	ng/mL	0	4.0		69 yrs.			Roche
PSA	ng/mL	0	5.0		79 yrs.			Roche
Bilirubin	umol/L		<21					Pathology Harmonisation
TNT	ng/L	<14						Roche
T. Protein	g/L	60	80					Pathology Harmonisation
Triglyceride	mmol/L	<1.7						Desirable
TSH	mIU/L	0.27	4.2					Roche
uric Acid	umol/L			200	430	140	360	Pathology Harmonisation
Urea	mmol/L	2.5	7.8					Pathology Harmonisation
Vitamin D	nmol/L	no	range					< 30 nmol/L: Deficiency 30-50 nmol/L: Insufficiency >50 nmol/L :Sufficient

Haematology

Test	Units	Adult Reference Ranges						Ref Range derived from
	Gender	Not stated		M		F		
WBC	10*9/L	4.0	10.0					Dacie & Lewis 12th edition
RBC	10*12/L			4.5	6.0	3.8	4.8	Dacie & Lewis 12th edition
Hb	g/L			130	170	110	150	Dacie & Lewis 12th edition
HCT	%	33.0	53.0					Dacie & Lewis 12th edition
MCV	fL	83.0	98.0					Dr Aldouri (Consultant Haematologist)
MCH	pg	27.0	32.0					Dacie & Lewis 12th edition
MCHC	g/L	315.0	345.0					Dr Aldouri (Consultant Haematologist)
RDW	fL	11.6	14					Dacie & Lewis 12th edition
PLT	10*9/L	150	400					Dacie & Lewis 12th edition
Neut	10*9/L	2.0	7.0					Dacie & Lewis 12th edition
Lymph	10*9/L	1.0	3.0					Dacie & Lewis 12th edition
Mono	10*9/L	0.2	1.0					Dacie & Lewis 12th edition
Eosinophils	10*9/L	0.02	0.5					Dacie & Lewis 12th edition
Basophils	10*9/L	0.0	0.1					Dacie & Lewis 12th edition

ESR

ESR	Gender	17-50 yrs.	51-60 yrs.	61 - 70	>70	Ref Range derived from
Mm in 1 hour	Male	10	12	14	30	Dacie & Lewis 12th edition
Mm in 1 hour	Female	12	19	20	35	Dacie & Lewis 12th edition

Coagulation

Test	Units	Adult Reference Ranges						Ref Range derived from
	Gender	All						
PT	Seconds	9.9	11.8					Sysmex
APTT	Seconds	21	30					Sysmex
Fib	g/L	1.7	4.2					Sysmex
INR		0.8	1.2					Sysmex
	Ref:	IM Appel , B Grimminck et al. Journal of Thrombosis and Haemostasis 2012;10:2254–2263						
		P Toulon, M Berruyer et al. Thrombosis and Haemostasis 2016;116:9-16						

20 SERVICE COMPLIMENTS AND COMPLAINTS

Should your experience of our services not reach the very high expectations we set out to achieve then we would appreciate you contacting the Pathology Team to discuss your complaint/concern:

Informal Complaints

In the first instance, please contact:

- Pathology Manager (Colin Brisley) colin.brisley@kims.org.uk or x8228
- Lead Biomedical Scientist and Quality Manager (Andrea Ferrige) andrea.ferrige@kims.org.uk or x8190

Formal Complaints

Please use the following contact:

- KIMS Hospital Quality Governance Team: complaints@kims.org.uk or 01622 237786 (x7786).

21 TRANSPORT OF SPECIMENS TO THE LABORATORY

KIMS Hospital holds a SLA with Delta UK Express LTD in order to cover all movement of samples between KIMS hospital and the referral laboratories in use (excluding TDL). This service is provided on a daily basis Monday – Saturday, and provides assurance that samples will be delivered within any set turnaround times. TDL has their own dedicated transport service provided directly from the TDL.

KIMS Hospital also has a SLA with Ajax courier company, Monday to Friday. They travel between KIMS Hospital, Sevenoaks Medical Centre and LycaHealth Orpington collecting Pathology samples/specimens for processing by KIMS Pathology Department. They pick up samples from LycaHealth Orpington once on a Saturday.

Clinical areas with KIMS Hospital to Laboratory Internal Sample Logistics

Specimens for pathology testing can be transported to the laboratory using one of the following methods:

1. In person from ward/clinical area to Laboratory Reception.
2. There are scheduled porter collections times around the hospital to deliver to Pathology
3. Extra collections can be organised via KIMS Hospital Porters using the MyPorter icon in KIMS Bookmarks folder.

22 PHLEBOTOMY SERVICE

An outpatient service is available within KIMS Hospital Main site, Sevenoaks Medical Centre and Outreach Clinics including LycaHealth Orpington. Bloods are taken on the wards by qualified and competent staff. The Phlebotomy services across KIMS Hospital and its Outreach clinics are controlled by the Clinical areas in which they are sited. Pathology does not have control over the various phlebotomy services. Pathology is a critical friend that gives advice.

When taking samples and specimens ask the patient their name and D.o.B if the patient is coherent, not 'is your name ***** or is your D.o.B **** as patients may say yes and these details may be wrong.

23 MANAGEMENT OF DATA AND INFORMATION

The proper management of data and information in the Laboratory is essential for the provision of the service.

The department is committed to meeting its information security obligations to meet the needs of users, clients, patients and staff with respect to confidentiality, integrity and availability, which are defined as follows:

Confidentiality: protecting information from unauthorised disclosure.

Integrity: safeguarding the accuracy and completeness of information and software.

Availability: ensuring information and vital services are available to users when required.

PAT-SOP-47 The Management of Data and Information describes the department's adherence to this standard.