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Title: Primary Sample Manual - Haematology

***Changes made since previous version:** Layout and alignment of FBC reference ranges tables amended. Methodologies no longer in use, including Westergren ESR, Sysmex CA660 coagulation assays removed. Test descriptions for FBC and ESR updated to remove references to specific disease.*

***Note**: Please refer to the document record on QPulse for the revision history of this document.*

CONTENTS:

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FULL BLOOD COUNT (FBC)

The Full Blood Count (FBC) is one of the most commonly requested laboratory tests, which focusses on the assessment of the cellular composition of peripheral whole blood. FBC results encompass the enumeration and specific characteristics of erythrocytes, leukocytes and platelets. Test results may provide insights into various clinical conditions, including anaemia, inflammatory response, specific neoplasms and bone marrow related disorders. The interpretation of FBC parameters should be considered in relation to the patient's overall health, medical history, and specific presentation.

Preparation of patients: There is no physical preparation for the FBC test.
Precautions: Frozen, clotted, or grossly haemolysed samples cannot be analysed.

Accredited	No	
Method	Sysmex XN2000 SOP: H57	Sysmex XN1000 SOP: BH09
Sample Requirements	Tube Type: Whole Blood EDTA Temperature: + 4ºC Miscellanous: N/A	Tube Type: Whole Blood EDTA Temperature: + 4ºC Miscellanous: N/A
Turn Around Time – Setup Schedule	Mon ✓ | Tue ✓ | Wed ✓ | Thu ✓ | Fri ✓ | Sat ✓ 24h	Mon ✓ | Tue ✓ | Wed ✓ | Thu ✓ | Fri ✓ | Sat ✓ 24h
Stability	2 days @ + 4ºC	2 days @ + 4ºC

FBC Adult Reference Ranges

Analyte (abbreviated)	Analyte full title	Units of Measurement	Adult Reference Ranges[a]	
			Male	Female
WBC	White cell count	10^9/L	4.0 - 10.0	4.0 - 10.0
RBC	Red cell count	10^{12}/L	4.5 - 5.5	3.8 - 4.8
HB	Haemoglobin	g/dL	13.0 - 17.0	12.0 - 15.0
HCT	Haematocrit	L/L	0.400 - 0.500	0.360 - 0.460
MCV	Mean corpuscular volume	fL	83 - 101	83 - 101
MCH	Mean corpuscular haemoglobin	pg	27 - 32	27 - 32
MCHC	Mean corpuscular haemoglobin concentration	g/dL	31.5 - 34.5	31.5 - 34.5
PLT	Platelet count	10^9/L	150 - 410	150 - 410
MPV	Mean platelet volume	fL	N/A	N/A
RDW	Red cell distribution width	%	11.6 - 14.0	11.6 - 14.0
#Neut	Neutrophil count	10^9/L	2.0 - 7.0	2.0 - 7.0
#Lym	Lymphocyte count	10^9/L	1.0 - 3.0	1.0 - 3.0
#Mono	Monocyte count	10^9/L	0.2 - 1.0	0.2 - 1.0
#Eos	Eosinophil count	10^9/L	0.02 - 0.50	0.02 - 0.50
#Baso	Basophil count	10^9/L	0.02 - 010	0.02 - 010

[a]Reference ranges sourced from Dacie and Lewis, Practical Haematology 12 edition (2017).

FBC Paediatric Reference Ranges[a]

Analyte (abbreviated)	Units of Measurement	Male/female < 1 year	Male/female 1 < 6 years	Male/female 6 < 12 years	Male 12 < 18 years	Female 12 < 18 years
WBC	10^9/L	6.00 - 16.00	5.00 - 15.00	5.00 - 13.00	3.88 - 10.49	3.88 - 10.49
RBC	10^{12}/L	3.90 - 5.10	4.00 - 5.20	4.00 - 5.20	4.28 - 5.59	3.73 - 5.02
HB	g/dL	11.1 - 14.1	11.0 - 14.0	11.5 - 15.5	13.5 - 17.2	11.3 - 15.2
HCT	L/L	0.300 - 0.380	0.340 - 0.400	0.350 - 0.450	0.381 - 0.499	0.323 - 0.462
MCV	fL	72.0 - 84.0	75.0 - 87.0	77.0 - 95.0	83.1 - 99.1	83.1 - 99.1
MCH	pg	25.0 - 29.0	24.0 - 30.0	25.0 - 33.0	28.3 -33.9	28.3 -33.9
MCHC	g/dL	32.0 - 36.0	31.0 - 37.0	31.0 - 37.0	32.1 - 36.6	32.1 - 36.6
PLT	10^9/L	200 - 550	200 - 490	170 - 450	164 - 382	164 - 382
MPV	fL	N/A	N/A	N/A	N/A	N/A
RDW	%	11.6 - 14.0	11.6 - 14.0	11.6 - 14.0	11.6 - 14.0	11.6 - 14.0
#Neut	10^9/L	1.00 - 7.00	1.50 - 8.00	2.00 - 8.00	1.56 - 6.52	1.56 - 6.52
#Lym	10^9/L	3.50 - 11.00	6.00 - 9.00	1.00 - 5.00	1.01 - 3.13	1.01 - 3.13
#Mono	10^9/L	0.20 - 1.00	0.20 - 1.00	0.20 - 1.00	1.01 - 3.13	1.01 - 3.13
#Eos	10^9/L	0.10 - 1.00	0.10 - 1.00	0.05 - 0.51	0.05 - 0.51	0.05 - 0.51

[a]Reference ranges sourced from Dacie and Lewis, Practical Haematology 12 edition (2017). Note reference ranges specific to basophils in table below.

FBC Paediatric Reference Ranges for basophil counts[a]

Analyte (abbreviated)	Units of Measurement	Male/female < 1 day	Male/female 1 < 7 days	Male/female < 14 years	Male/female < 18 years
#Baso	10^9/L	0.00 - 0.64	0.00 - 0.25	0.00 - 0.23	0.02 - 0.15

[a]Reference ranges sourced from Dacie and Lewis, Practical Haematology 12 edition (2017).

ERYTHROCYTE SEDIMENTATION RATE (ESR)

The Erythrocyte Sedimentation Rate (ESR) is a blood test which measures the rate at which red blood cells (erythrocytes) settle at the bottom of a tube over a specific period, usually 1 hour. The ESR is affected by the presence of plasma proteins, such as fibrinogen, IgM, alpha2-macroglobulin and other acute phase proteins, which encourage erythrocyte agglomeration. It is important to note that while ESR is a useful tool, it is not specific to any particular disease. A high ESR can be seen in various conditions, and additional tests are often needed to achieve an accurate diagnosis. The ESR, therefore, forms a part of a broader spectrum of diagnostic tools which healthcare professions use to assess and monitor inflammatory and infectious disease.

Preparation of patients: There is no physical preparation for the ESR test.

Precautions: The ESR should not be used to screen healthy persons for disease.

Accredited	No
Method	Haematology – Capillary photometric-kinetic technology SOP: H9
Sample Requirements	Tube Type: Whole Blood (Lavender cap) Temperature: + 4ºC Miscellanous: N/A
Turn Around Time – Setup Schedule	Mon ✓ Tue ✓ Wed ✓ Thu ✓ Fri ✓ Sat ✓ 24h
Stability	2 days @ + 4ºC
Units - Reference Ranges	mm/hr

ESR Ref Ranges	Male	Female
>50 Years	0-≤12	0-≤15
<50 Years	0-≤8	0-≤10

Source	Reference ranges for the ESR assay are derived in house. Data was obtained from a clinical normal population and statistics generated using the Graph Pad statistics module. Data was analysed for Gaussian distribution and reference ranges derived using either parametric or non-parametric statistics. A copy of the data is kept in the QA department.

INFECTIOUS MONONUCLEOSIS

Infectious mononucleosis (glandular fever) is an acute infectious disease caused by the Epstein-Barr virus and primarily affects lymphoid tissue. It is characterized by the appearance of enlarged and often tender lymph nodes, enlarged spleen, and abnormal lymphocytes in the blood. Patients usually, but not always, develop a transient heterophile antibody response.
The detection of heterophile antibodies of Infectious Mononucleosis by the agglutination of sheep red cells was first reported by Paul and Bunnel. Subsequent work identified the need for differential absorption of sera to remove non-infectious mononucleosis heterophile antibodies. Fetcher and Woolfolk showed that antigens obtained from bovine erythrocytes were more effective than those antigens obtained from either sheep or horse erythrocytes.

Preparation of patients: There is no physical preparation for the infectious mononucleosis test.

Precautions: IgG and IgM values obtained with different manufacturers' assay methods may not be used interchangeably. The magnitude of the reported IgG or IgM level cannot be correlated to an endpoint titre.

Accredited	No
Method	Haematology- Immunoassay SOP: H20
Sample Requirements	Tube Type: Whole blood serum or plasma Temperature: + 4ºC Miscellaneous: N/A
Turn Around Time – Setup Schedule	24h Mon ✓ Tue ✓ Wed ✓ Thu ✓ Fri ✓
Stability	3 days @ + 4ºC
Result	Positive or negative
Source	'Clearview IM II' Kit Insert, Alere group.

SAMPLE REQUIREMENTS FOR COAGULATION TESTS

PROCEDURE

Sample Requirements and Collection

- Patients should be relaxed pre-venepuncture. Excessive stress and exercise will increase FVIII, vWF antigen and fibrinolysis. Venous occlusion should be avoided.
- Difficult venepuncture with trauma may lead to platelet activation with release of PF4 from alpha granules.
- Venous blood should be collected into coagulation tubes containing Sodium Citrate 3.2%, 0.105M, 3ml.
- Specimens must be mixed immediately post venepuncture to avoid clot activation, by GENTLY inverting the tubes 5 to 10 times.
- The ratio of whole blood to anticoagulant is crucial. Under-filled specimens will not be processed as over- or under-filled tubes can adversely affect results.
- Any warfarin treatment should be mentioned on the request form.

Transportation and Storage

- PT/INR specimens should ideally be analysed within 12 hours of collection and transported to the laboratory at room temperature.
- APTT and Fibrinogen should ideally be analysed within 4 hours of collection. Where this is not possible please centrifuge at room temperature (RT) @3000rpm (1500g) for at least 15 minutes, and then carefully remove the plasma from the cells, transfer to a fresh plastic plain tube and freeze at -20^{o}C.
- Non-frozen coagulation specimens should be transported at RT ASAP to avoid deterioration of labile factors V and VIII.
- Collection of blood through intravenous lines that have been previously flushed with heparin should be avoided. In the event blood is drawn from an indwelling catheter, the line should be flushed with 5ml of saline, and the first 5ml of blood or 6 times the line volume be drawn off and discarded before coagulation tube is filled.

Plasma Sample Stability (CLSI H21-A5)

- PT 24 hours @ RT or 2 weeks @-20^{o}C
- APTT 4 hours @ RT or 2 weeks @-20^{o}C & 12 Months @-70^{o}C
- Fibrinogen- 4 hours @ RT

FIBRINOGEN (CLAUSS METHOD)

Clauss developed a simple method for the quantitative determination of Fibrinogen by measuring the clotting time of dilute plasma after the addition of Thrombin. The clotting time is inversely proportional to the Fibrinogen concentration. The clotting time obtained in this manner is then compared with that of a standardised Fibrinogen preparation. The plasma must be diluted to provide a low level of potential inhibitors, e.g. FDP's and Heparin. A strong Thrombin solution is utilised in order to ensure that the clotting time is independent of Thrombin concentration over a broad range.

Preparation of patient: Patients should be relaxed pre-venepuncture. Excessive stress and exercise will increase Factor VIII, vWF antigen and fibrinolysis. Veno-occlusion should be avoided.

Precautions: This test is not recommended for patients with active bleeding, acute infection or illness, or in those patients who have received blood transfusions within four weeks. Drugs that may increase Fibrinogen levels include Oestrogens and oral contraceptives. Drugs that may cause decreased levels include anabolic steroids, androgens, Phenobarbital, Urokinase, Streptokinase, and Valproic acid.

Accredited	No
Method	Stago Compact Max, Stago Satellite Max SOP: H60, H56
Sample Requirements	Tube Type: Sodium Citrate Plasma 3.2% 0.105M **Temperature**: 4 hours Room temperature or 2 weeks @ -20ºC. If an expected delay in transporting samples to the laboratory samples should be centrifuge, separated & send as frozen within 4 hours of blood collection. Miscellaneous: N/A **Collection: Cf. Special requirement for Coagulation test**
Turn Around Time – Setup Schedule	24h Mon ✓ Tue ✓ Wed ✓ Thu ✓ Fri ✓
Stability	Whole blood: 4 hours, unless centrifuged at room temperature at 1500g, separated and the plasma frozen. Can only be thawed once. If an expected delay from collection time to receipt in the laboratory, suggest send frozen sample. (SIEMENS Kit Insert & CSLI H21-A5)
Units - Reference Ranges	1.8 – 3.6 g/L
Source	Dacie and Lewis, Practical Haematology 12th edition, 2017

PROTHROMBIN TIME (PT)

The PT test (scientific name- tissue activated induced coagulation time) has been in clinical practice for over 60 years. The first standardised one-stage PT test was devolved by Dr. Armand Quick in 1932. It has now become the basic coagulation screening test for the diagnosis of acquired and congenital deficiencies of clotting factors in the Extrinsic pathway. The assay was designed to measure a coagulation defect before the introduction of oral anticoagulants, and later adapted for monitoring their dosage. The PT reflects changes in the Extrinsic factors II, VII and X, three of the principle clotting factors depressed by Coumarin drugs, and FV, not reduced by oral anticoagulation. It can also be used to assess the protein synthesis capability of the liver in chronic or acute hepatic disorders. The test depends on the activation of Factor X in the presence of Factor VII by Tissue Factor (TF) and bypassing of the Intrinsic clotting pathway. The speed of the reaction and the responsiveness of the PT to deficiencies of clotting factors depend upon the properties and concentration of the TF as well as on the clotting factor concentrations.

Preparation of patient: Patients should be relaxed pre-venepuncture. Excessive stress and exercise will increase Factor VIII, vWF antigen and fibrinolysis. Veno-occlusion should be avoided.

Precautions: The doctor should check to see if the patient is taking any medications that may affect test results. This precaution is particularly important if the patient is taking Warfarin, because there are a number of medications that can interact with Warfarin to increase or decrease the PT time.

Accredited	No
Method	Stago Compact Max, Stago Satellite Max SOP: H60, H56
Sample Requirements	Tube Type: Sodium Citrate Plasma 3.2% 0.105M **Temperature**:12 hours Room Temperature or 2 weeks @ -20ºC Miscellaneous: N/A **Collection: Cf. Special requirement for Coagulation test**
Turn Around Time – Setup Schedule	24h Mon ✓ Tue ✓ Wed ✓ Thu ✓ Fri ✓
Stability	Whole blood: 12 hours at room temperature. If a longer delay is expected in transport to the laboratory, centrifuge at 1500g for at least 15 minutes, separate, and freeze plasma. Can only be thawed once. (SIEMENS Kit Insert & CSLI H21-A5)
Units - Reference Ranges	PT 11.0 – 16.0 Seconds INR – Not applicable
Source	Dacie and Lewis, Practical Haematology 12th edition, 2017

ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)

This test is also known as the Partial Thromboplastin Time with Kaolin (PTTK) and the Kaolin Cephalin Clotting Time (KCCT) reflecting the methods used to perform the test. The APTT is the main screening test for the Intrinsic clotting system and is the second most common coagulation test being exceeded in frequency only by the prothrombin time.

The Partial Thromboplastin of the APTT is a phospholipid extract of animal tissue or from vegetable sources. The phospholipids act as a platelet substitute in the Intrinsic system. The test incorporates an activator, in the absence of added Thromboplastin, which shortens the test and increases the precision and reproducibility by eliminating the variable effects of contact from glass surfaces and by effecting maximum activation. The activator is used to stimulate the production of FXIIa by providing a surface for the function of high molecular weight Kininogen, Kallikrein and FXIIa. The contact activation occurs for a time at 37ºC. Calcium is then added to trigger further reactions and the time required for clot formation measured. Standardised Phospholipids are required to form complexes, which activate FX and Prothrombin, which allows the test to be conducted in patient Platelet poor plasma (PPP).

The test depends not only on the contact factors and factors VIII and IX, but also on the reactions with factors X, V, Prothrombin and Fibrinogen. It is also sensitive to the presence of circulating anticoagulants (inhibitors) and Heparin.

Preparation of patient: Patients should be relaxed pre-venepuncture. Excessive stress and exercise will increase Factor VIII, vWF antigen and fibrinolysis. Veno-occlusion should be avoided.

Precautions: APTT results may be affected by many commonly administered drugs and further studies should be made to determine the source of unexpected abnormal results. Oral contraceptive and Oestrogen therapy in males have been found to decrease APTT in vivo. Conversely, Heparin, Warfarin, Lupus anticoagulant and radio therapy have been found to increase APTT in vivo.

Accredited	No
Method	Stago Compact Max, Stago Satellite Max SOP: H60, H56
Sample Requirements	Tube Type: Sodium Citrate Plasma 3.2% **Temperature:** 4 hours Room temperature or 2 weeks -20ºC Miscellaneous: N/A **Collection: Cf. Special requirement for Coagulation test**
Turn Around Time – Setup Schedule	24h Mon ✓ Tue ✓ Wed ✓ Thu ✓ Fri ✓
Stability	Whole blood: 4 hours, unless centrifuged at room temperature at 1500g for 15 min, separated and the plasma frozen. Can only be thawed once. If an expected delay from collection time to receipt in the laboratory, suggest send frozen plasma. (BD Ref. VS5966 Evaluation of 0.109M BD Vacutainer® Plus Plastic and 0.105M BD Vacutainer® Glass Sodium Citrate Tubes for PT and APTT Using the Sysmex CA - 1500 Analyzer. BD, Franklin Lakes, NJ, USA June 2002; CSLI H21-A5)
Units - Reference Ranges	26.0 – 40 seconds
Source	Dacie and Lewis, Practical Haematology 12th edition, 2017

BLOOD PARASITOLOGY - MALARIA

Malaria is caused by a group of related intracellular protozoan pathogens of the genus Plasmodium. These species exhibit a complex life cycle reliant on a mammalian host and anopheles mosquito vector. In the human host they are obligate intracellular pathogens infecting initially the liver in the sporozoite form. In the liver the parasites replicate and develop into merozoites which are then released into the blood stream. These infect the erythrocyte and begin a restricted life cycle. Each parasite may develop into a schizont (a cluster of infectious units which may invade further erythrocytes) or a gametocyte (the sexual form which may be transferred to the anopheles mosquito upon taking a blood meal). Re-infection of the liver does not occur.

Suspected malaria is a medical emergency. Sampling and processing of the blood sample must not be delayed if malaria is suspected. Five primary species of malaria have been identified in humans: P.*falciparum*, P.*vivax*, P.*ovale* P.*malariae* and P.*knowlesi.* Their geographic distribution is unique for each species.
Blood should ideally be taken direct from the patient's finger or ear & the films prepared at the bedside or in the clinic. When this is not possible blood taken into anticoagulant (EDTA) can be used. Thick & thin blood films should be made as soon as possible, certainly less than 2 hours after the EDTA blood was drawn, to minimise morphological changes in the parasites. Parasite and red cell morphology can be seriously affected if the blood has been in anticoagulation for too long.
Where there is a strong clinical suspicion if the first films are negative, blood should be taken and films made and checked at least two times over the first 24 hours and further films examined every 12 hours after that if strongly clinically indicated.

Preparation of patients:
Travel history should be recorded and any clinical details recorded on the request form.
In symptomatic patients please phone the laboratory prior to sending the sample.

Precautions: Global distribution of malaria is restricted to areas endemic to the anopheles mosquito. Latent infections of some species may occur due to hypnozoites stored in the liver. P. *knowlesi* is morphologically indistinguishable from P. *malariae* on blood film preparations.

Accredited	No
Method	Haematology – Thick & Thin Blood film & CareStart Malaria Rapydtest antigen kit (Kit Insert: APACOR CareStart RAPYDTEST- APA059 V7 04/2017) SOP: H47
Sample Requirements	Tube Type: Whole Blood K2/K3 EDTA (Lavender cap) Temperature: + 4ºC Miscellanous: Observe periodicity where applicable.
Turn Around Time – Setup Schedule	24h Mon ✓ Tue ✓ Wed ✓ Thu ✓ Fri ✓
Stability	Blood films Thick & thin need to be made less than 2 hours after the blood EDTA was drawn. 2 days @ 2 - 8ºC (CareStart RAPYDTEST Malaria Antigen Kit)
Units - Reference Ranges	% parasitaemia (applicable to P. *falciparum* & P. *knowlesi* infection) No reference ranges applicable. Genus and species reportable.
Source	WHO Guideline: 'The Laboratory Diagnosis of Malaria'. J.W Bailey, B.J Bain, J Parker-Williams and P.Chiodini for the General Haematology Task Force of the British Committee for Standards in Haematology. http://www.bcshguides.com/documents/malaria-bcsh.2005.pdf Malaria Reference Laboratory. www.malaria-reference.co.uk

D-DIMER

D-dimer is a degradation product of cross-linked fibrin. The D-dimer concentration is a measure of the fibrinolytic activity of plasmin in the vascular system. Elevated concentrations of D-dimer indicate increased coagulatory and fibrinolytic activity. With a normal D-dimer value, acute deep vein thrombosis and pulmonary embolisms may be ruled out with high reliability.

Preparation of patients: There is no physical preparation for the D-Dimer test.

Precautions: No modifications to change diet, medications, or activity required before this test. Phlebotomists should enquire about any blood thinners or anticoagulant medication any diseases like liver disease and rheumatoid arthritis. There are some herbs that are also able to replicate the effects of blood thinning medication.

Accredited	No
Method	Stago Compact Max SOP H60
Sample Requirements	Tube Type: Sodium Citrate 3.2%, Temperature: 15-25°C (Do not refrigerate or freeze) Miscellanous: N/A
Turn Around Time – Setup Schedule	Same Day
Stability	8 hours @ 15-25°C
Units - Reference Ranges	0.0-0.50 µg/mL
Source	BD Ref. VS5966 Evaluation of 0.109M BD Vacutainer® Plus Plastic and 0.105M BD Vacutainer® Glass Sodium Citrate Tubes for PT and APTT Using the Sysmex CA - 1500 Analyzer. BD, Franklin Lakes, NJ, USA June 2002

Mon	Tue	Wed	Thu	Fri
✓	✓	✓	✓	✓

RETICULOCYTES

The process of red blood cell production starts in the bone marrow, where cells pass through various stages of development, becoming increasingly mature. The reticulocyte is the final stage of the development of the red blood cell before full maturation. Reticulocyte is an immature red blood cell without a nucleus, having a granular or reticulated appearance when suitably stained. They are present in normal blood in very low numbers, increased numbers are maybe the product of a pathological process or could be the body's response to pregnancy, therapy with iron B12, or folate or to blood loss. Reticulocytes are not part of the full blood count so they need to be specifically requested.

Preparation of patients: There is no physical preparation for the test.

Precautions: Frozen, clotted, or grossly haemolysed samples cannot be analysed.

Accredited: No

Method: Haematology – SYSMEX XN2000
SOP: H57

Sample Requirements: Tube Type: Whole Blood (Lavender cap)
Temperature: + 4ºC
Miscellanous: N/A

Turn Around Time – Setup Schedule: 24h

Mon	Tue	Wed	Thu	Fri	Sat
✓	✓	✓	✓	✓	✓

Stability: 2 days @ + 4ºC

Units - Reference Ranges: Reference Range for both Male & Female

Age	Absolute Reference Range	Age	% Reference Range
0 - 1 day	324 - 617 x10^9/L	0 - 1 day	1.72 - 8.62%
1 - 5 days	85 - 400 x10^9/L	1 - 5 days	1.9 - 9.1%
5 days - 1mth	34.2 -724 x10^9/L	5 days - 1 mth	0.1 - 6.9%
1 - 3 mths	21.3 - 205 x10^9/L	1 - 3 mths	0.1 - 6.27%
3 - 12 mths	8.0 - 171 x10^9/L	3 - 12 mths	0.1 - 4.7%
1 - 3 yrs	55.6 - 120 x10^9/L	1 - 3 yrs	0.35 - 2.95%
3 - 7yrs	16.4 - 120.7 x10^9/L	3 - 7 yrs	0.25 - 2.57%
Adult	35.2 - 122.8 x10^9/L	Adult	0.75 - 2.7%

Source: Haematology, G. Moore, G. Knight & A. Blann, 2nd edition, Oxford 2016.
The RR was derived from the Drogheda OLOL SYSMEX XN-1000 Analyser. The RR from OLOL Drogheda Our Ladys Hospital for Sick Children Crumlin, Great Ormond Street Hospital, Dacie & Lewis Practical Haematology 10th Edition and Pediatric Haematology 3rd Edition. This is based on the correlation study between OLOL hospital and Eurofins-Biomnis during validation and compatible platforms, reagents, calibrators and controls.

SICKLE CELL SCREENING TEST

Sickle cell disease is an inherited condition characterised by the presence of Haemoglobin S (HB-S). Hb-S exists in a homozygous state (S/S) known as Sickle Cell Anaemia or in a heterozygous state (A/S) known as Sickle Cell Trait. Homozygous individuals (S/S) commonly exhibit symptoms of severe haemolytic anaemia and/or vascular occlusions. Heterozygous individuals (A/S) are usually asymptomatic. Hb-S may be present with other haemoglobins, such as Haemoglonbin A, C or D, or with thalassemia, a condition that interferes with the synthesis of normal haemoglobin.
Under conditions of low oxygen tension, the heterozygous (A/S) form can cause erythrocytes to form the characteristic sickle-shaped tactoids. The formation of these irreversible sickled red blood cells causes the onset of the acute symptoms. Detection of both the homozygous and heterozygous condition is important so high-risk individuals can be identified and their symptoms reduced.

SICKLEDEX® kit is a qualitative solubility test for testing the presence of sickling haemoglobins in human blood. Deoxygenated Hb-S is insoluble in the presence of a concentrated phosphate buffer solution and forms a turbid suspension that can be easily visualised. Normal Haemoglobin A and other haemoglobins remain in solution under these conditions. These different qualitative outcomes allow for the detection of sickle cell disease and its traits.
SICKLEDEX uses Saponin to lyse the red blood cells. Sodium Hydrosulfite then reduces the released haemoglobin. Reduced Hb-S is insoluble in the concentrated phosphate buffer and forms a cloudy turbid suspension. Other sickling haemoglobin subtypes may also give a positive result.

Preparation of patients: There is no physical preparation for the test.

Precautions: Frozen, clotted, or grossly haemolysed samples cannot be analysed.

Accredited	No
Method	Haematology- qualitative solubility test for testing the presence of sickling haemoglobins SOP: H53
Sample Requirements	Tube Type: Whole blood EDTA Temperature: + 4ºC Miscellaneous: N/A
Turn Around Time – Setup Schedule	24h Mon ✓ Tue ✓ Wed ✓ Thu ✓ Fri ✓
Stability	3 days @ + 4ºC
Result	Positive or negative
Source	Sickledex kit insert, Streck – 350512-13, 05-2016.