



User Manual

Reviewed date: 13 August 2026

INDEX

1. GENERAL.....	3
2. LABORATORY LOCATIONS, CONTACT DETAILS AND OPERATING HOURS	3
3. GENERAL ANALYTE LIST.....	7
4. SOP 5005 RECEIVING OF SPECIMEN	39
5. PHLEBOTOMY PROCEDURE	39
6. POPI ACT CONSENT DECLARATION	48
7. SOP-6002 FEEDBACK AND COMPLAINT PROCEDURE	52
8. REFERENCES.....	53

FIGURES

FIGURE 1: SPUTUM COLLECTION DIAGRAM.....	44
FIGURE 2: FEEDBACK AND COMPLAINT REGISTER	53

TABLES

TABLE 1: PRETORIA EAST LABORATORY CONTACT DETAILS.....	3
TABLE 2: REFERENCE LABORATORY CONTACT DETAILS	4
TABLE 3: BENONI LABORATORY CONTACT DETAILS.....	4
TABLE 4: WILGERS LABORATORY CONTACT DETAILS	4
TABLE 5: PATHOLOGISTS CONTACT INFORMATION	4
TABLE 6: HEAD OF DEPARTMENT/LABORATORY MANAGER/S CONTACT DETAILS	5
TABLE 7: ACCOUNTS AND ADMINISTRATION CONTACT DETAILS	5
TABLE 8: ONCOLAB DIAGNOSTIC LABORATORY SITES.....	6
TABLE 9: GENERAL ANALYTE LIST	7
TABLE 10. ORDER OF DRAW – AND NUMBER OF INVERSIONS, MINIMUM VOLUME	41

APPENDICES

APPENDIX A: FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE LIST	38
--	----

1. GENERAL

1.1.1 Oncolab Diagnostics provides state of the art haematology and cellular diagnostic and therapeutic solution for, but not limited to patients with haematological diseases being treated at the centre.

1.1.2 Services offered:

1.1.2.1 Molecular Diagnostics

1.1.2.2 Genetics

1.1.2.3 Haematology

1.1.2.4 Chemical Pathology

1.1.2.5 Histology (bone marrows only)

1.1.2.6 Flow cytometry

1.1.2.7 Phlebotomy

2. LABORATORY LOCATIONS, CONTACT DETAILS AND OPERATING HOURS

2.1.1.1 Oncolab diagnostics
Room A07
Netcare Pretoria East Hospital
Corner Netcare and Garsfontein road
Moreleta park
Pretoria

Table 1: Pretoria East Laboratory contact details

Contact Details	
General landline	012 993 2555
Laboratory after hours	071 600 3315
Phlebotomy	066 507 2258

2.1.1.2 Jaqueline Drive 562
Garsfontein
Pretoria

Table 2: Reference laboratory contact details

Contact Details	
General landline	012 110 4027
Laboratory after hours	071 600 3315

2.1.1.1 ABJ Benoni Oncology centre
140 Princes avenue
Benoni

Table 3: Benoni Laboratory contact details

Contact Details	
General landline	011 422 3355
Laboratory after hours	071 600 3315

2.1.1.1 ABJ Wilgers Oncology centre
Denneboom road
Die Wilgers
Pretoria

Table 4: Wilgers laboratory contact details

Contact Details	
General landline	012 807 2744
Laboratory after hours	071 600 3315

2.1.2 The pathologists take full responsibility of all results and are available for consultation and advice:

2.1.2.1 Laboratory services, including advisory and interpretive services available to meet the need of patients and clients using the laboratory services.

Table 5: Pathologists contact information

Pathologist	Contact number	Email address	Discipline
Dr T Gerdener	072 607 8945	theo@oncolab.co.za	Haematology/ Molecular / Genetics
Dr R Marshall	083 504 7906	robyn@oncolab.co.za	Haematology/ Molecular / Genetics
Dr K Ungerer	083 289 0334	kobusu@oncolab.co.za	Chemical Pathology

2.1.3 Heads of departments/Laboratory managers:

Table 6: Head of department/Laboratory manager/s contact details

HOD/LM	Email address	Discipline
Tania Venter	taniav@oncolab.co.za	Benoni and Wilgers, Operations manager
Hannelie Bothma	hannelieb@oncolab.co.za	Garsfontein: Genetics/Flowcytometry/Molecular laboratory
Trudy Nkwane	trudyn@oncolab.co.za	Pretoria East: Chemistry & Haematology laboratory
Michelle Bronze	michelleb@oncolab.co.za	Manager Director

2.1.4 Accounts and administration:

Table 7: Accounts and administration contact details

Contact details		
Queries		010 753 2202
Accounts Manager	Judy Scheepers	010 753 2202
Finance Manager	Mariska Kloppe	012 110 4027
Banking details		
Account holder	Gerdener & Partners Inc.	
Bank	ABSA	
Account number	40834300374	
Branch	Universal (632005)	

2.1.5 Some of these services are subcontracted to other facilities. Only facilities that offer a competitive quality service with a focus on time delivery that complies with ISO 15189 will be considered.

- 2.1.6 Not all Oncolab Diagnostics facilities are operating as a 24-hour laboratory and patient samples will occasionally be referred to subcontracted referral laboratories.
- 2.1.7 All relevant information is available on the Oncolab Diagnostics website; <https://oncolab.co.za>
- 2.1.8 Oncolab Diagnostics operates from four sites as indicated by the below table:

Table 8: Oncolab Diagnostic laboratory sites

Pretoria East Stat laboratory (PE)	Garsfontein Reference Laboratory (GF)	Benoni – Stat Laboratory (Ben)	Wilgers Hospital (Wilg)
Haematology	Molecular Studies	Haematology	Haematology
Chemistry	Chromosome Analysis	Chemistry	Chemistry
Flowcytometry	Flowcytometry	Phlebotomy	Phlebotomy
Cytochemistry	FISH (Fluorescent <i>in situ</i> Hybridization)		
Phlebotomy			

3. GENERAL ANALYTE LIST

Table 9: General analyte list

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
A								
ABL Kinase mutation (also refer to CML Mutation TKI)	N/A	N/A	1 x EDTA	2 weeks	Monday to Friday	3 days	Ampath NRL (Alternatively NHLS)	N/A
ADAM TS13	N/A	N/A	3 x Citrate	N/A	Monday to Friday	7 days	Ampath KZN	Request instructions from Ampath depot before the sample collection. Samples are accepted on Mondays – Thursdays.
Alpha-feto Protein	0 – 10	µg/l	1xSST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Albumin	0D-<5D: 28-44 5D-<15Y:38-54 15Y-<19Y:32-45 19Y-<61Y:35-52 61Y-90Y:32-46 >90Y:29-45	g/l	1x SST/Barricor blood	BEN/Wilg2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
ALP (Alkaline phosphatase)	M(19Y-60Y): 53-128 F(19Y-60Y):42-98 M(>60Y):56-119 F(>60Y):53-141	U/l	1x SST/Barricor blood	BEN/Wilg2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
ALT (Alanine aminotransferase)	M(0D-<1Y):13-45 F(1D-<1Y):13-45 M(1Y-<61Y):10-40 F(1Y-61Y):7-35 M(61Y-90Y):13-40 F(61Y-90Y):10-28 M(>90):60-38 F(>90Y):5-24	U/l	1x SST/Barricor blood	BEN/Wilg2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Alpha Galactomannan	0.0-0.50		1x SST blood	7 days	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Ammonia (NH3)	M: 15-55 F: 11 - 48	umol/L	1x EDTA blood	24 hours	24/7	2 hours	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	Keep on ice
Amylase	<110	U/l	1x SST blood 5 ml fluid 5 ml random urine	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Amikacin Level (trough/peak)	PEAK Level: Interment dosing: 15-30 Single daily (pulse) dosing: 56-64 Trough Level: Interment dosing: 5-10 Single daily (pulse) dosing: <1	ug/ml	1x SST blood	24 hours	24/7	1 day	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	Time of sampling PEAK 60 minutes after bolus IV/IM dose or 60 minutes after the start of a 30-minute IV infusion. Trough Immediately prior the next dose

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
ANA (Anti-Nuclear Abs)	N/A	N/A	1 x SST blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	Lipemic, hemolyzed or contaminated serum may cause erroneous results
ANCA (Anti-Neutrophil Cytoplasmic Abs)	N/A	N/A	1x SST blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
ANF (Refer to ANA)	N/A	N/A	1x SST blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Anti Factor X activity	N/A	IU/ml	1x Citrate blood	24 hours	24/7	72 hours	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Anti-Thrombin III	N/A	N/A	2x Citrate blood	24 hours	24/7	24 hours	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	Separate plasma before transport to avoid hemolysis
ST (Aspartate aminotransferase)	M/F(0D-<11D):47-150 M/D(11D-<2Y):9-80 M(2Y-<61Y):15-40 F(2Y-<61Y):13-35 M(61Y-90Y):19-48 F(61Y - 90Y):9-36 M(>90):11-38 F(>90):18-30	U/l	1x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Auto-immune Profile	N/A	N/A	1x SST blood 1 x EDTA blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
B								
BCR/ABL1 p210	N/A	N/A	4 x EDTA blood	72 hours	Monday to Friday	72 hours	N/A	N/A
BCR/ABL1 p190	N/A	N/A	4 x EDTA blood	72 hours	Monday to Friday	72 hours	N/A	N/A
Beta-2-Macroglobulins	M/F(OD-60Y):0.8-2.4 M/F(>60Y): ≤3.0	mg/l	1x SST blood	2 hours	24/7	7 days	N/A	N/A
B-HCG Quantitative	0 – 4.9 Negative 5 – 25 Equivocal >25 Positive	mIU/ml	1x SST blood	24 hours	24/7	24 hours	Ampath/Lancet Pretoria east/ Pathcare Vermaak	N/A
Bicarbonate (CO2)	OD-108Y:21-29	mmol/L	1x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Bilirubin (Direct)	OD-<1M: 2-7 1M-108Y:<34	umol/L	1x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Bilirubin (Total)	0D-<1D:24-149 1D-<3D:58-197 3D-5D:26-205 >5D-<61Y:2-21 61Y-90Y:2-19 >19Y:2-15	umol/L	1x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Blood cultures	N/A	N/A	1x Aerobic 1x Anaerobic bottle	Minimum 5 days	24/7	7 days	Ampath NRL	N/A
Blood gas	N/A		1x Heparin syringe blood		24/7	1 hour	Ampath NRL	Keep on ice if not analyzed within 15 minutes
Blood group	N/A	N/A	1x EDTA blood	24 hours	24/7	3 Days	Pathcare Vermaak	Need to reach the laboratory preferably within 24 hours after collection but no later than 72 hours.
BNP (NT-pro-BNP)	< 125	pg/ml	1x Barricor blood	24 hours	24/7	1 Day	Ampath/Lancet Pretoria east/ Pathcare Vermaak	
C								
Cancer markers	Refer to individual analytes	U/ml	1 x SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	HCG AFP CA72-4
CA 15-3	0 – 23.5	U/ml	1 x SST blood	2 hours	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
CA 19–9	0 – 35	U/ml	1 x SST blood	2 hours	24/7	7 days	N/A	N/A
CA 125	0 – 35	U/ml	1 x SST blood	2 hours	24/7	7 days	N/A	N/A
CEA	0 – 3	ng/ml	1 x SST blood	2 hours	24/7	7 days	N/A	N/A
Calcium (albumin included)	2.15 – 2.50	mmol/L	1x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Cardiac Profile (CK, CKMB, Myoglobin, Trop T)	Refer to individual analytes		1x SST/Barricor blood	24 hours	24/7	7 days	Ampath/Lancet Pretoria east/ Pathcare Vermaak	N/A
CD3 & CD34 enumeration	N/A	Cells/ul	1 x EDTA blood	4 hours	24/7	8 hours	N/A	Stem cells or peripheral blood
Chimerism genotyping	N/A	%	1 x EDTA blood/ 3 x buccal swab/product	30 days	Monday to Friday (batched 1xpw)	7 days	N/A	1 x EDTA from donor and 1 x EDTA from patient pre-transplant
Chimerism monitoring	N/A	%	4 x EDTA (full) blood	7 days	Monday to Friday, (batched 1xpw)	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Chloride	0D-<1M:98-113 1M-90Y:98-107 >90Y-108Y:98-111	mmol/l	1x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Cholesterol	<5.2	mmol/l	1x SST/Barricor blood	2 hours 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Chromogranin A	0 – 85	ng/ml	1 x SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Chromosome studies (Refer to Karyotyping)	N/A	N/A	1 x Bone Marrow or Peripheral blood in Sodium Heparin (>20% Blast if Peripheral Blood)	30 Days	Monday to Friday	48 hours	N/A	Need to reach the laboratory preferably within 24 hours after collection but no later than 48 hours. Transport at RT
Coombs (Direct)	N/A	N/A	1x EDTA blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
C-reactive protein	OD-108Y:2.0-10.0	mg/L	1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Creatinine	M/F: OD-<5D:27-88 5D-<1Y:18-35 1Y-<10Y:27-62 10Y-<18Y:44-88 M(61Y-90Y):71-115 F(61Y-90Y):53-106 M(>90Y):88-150 F(>90Y):53-115	umol/L	1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Creatine Kinase (CK)	M: 39 – 308 F: 26 – 192	U/l	1 x SST blood	24 hours	24/7	7 days	N/A	N/A
CK-MB	M: 0 – 7.6 F: 0 – 5.2	ng/ml	1 x SST blood	24 hours	24/7	7 days	N/A	N/A
CML Mutation TKI (Refer to ABL Kinase mutation)	N/A	N/A	2 x EDTA	2-4 weeks	Monday to Friday	-	Ampath NRL (Alternatively NHLS)	N/A
Cryoglobulins	N/A	N/A	Confirm with the referral laboratory	-	24/7	-	Pathcare Vermaak	Arrange test with the referral lab.
CSF (Cerebrospinal Fluid) Profile, Biochemistry, MCS, Cell count, Flowcytometry, Cytology	N/A	N/A	2 x CSF (no additives)	2 hours	24/7	7 days	Ampath/Lancet Pretoria east/ Pathcare Vermaak	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Cyclosporin A Levels	N/A	ng/ml	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Cytomegalovirus Viral load (CMVVVL)	N/A	IU/ml	1 x EDTA blood	7 days	Monday to Friday (Batch 2x Week)	7 days	N/A	Post allogeneic transplant, weekly for 14 weeks
CMV IgM	0.0-17.9	IU/ml	1 X SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
CMV IgG	0.0-13.9	IU/ml	1 X SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Cytochemistry	N/A	N/A	Preferable 10 x Unstained BM/PM slide	5 days	Monday to Friday	1 year	N/A	N/A
D								
D-Dimer	0 – 0.50	mg/l	1 x Citrate blood	1 hour 4 hours (Morning rounds)	24/7	4 hours	N/A	N/A
Direct LDL	<3.0	mmol/l	1x SST blood	2 hours 5 hours (Morning rounds)	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
E								
EBV ab	N/A	N/A	1 x SST	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia Pathcare Vermaak	N/A
EBV viral load	N/A	c/ml	1 x EDTA blood	48 hours	24/7	7 days	Ampath NRL / Lancet Pencardia Pathcare Vermaak	N/A
Electrolytes (Na, K, CL, TCO2, anion gap)	Refer to individual test		1 x SST blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
eGFR	≥90	ml/min/ 1.73m ²	1 x SST blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Erythropoietin levels	N/A	48 hrs	1 x SST blood	24 hours	24/7	7 days	Ampath NRL / Lancet Pencardia Pathcare Vermaak	N/A
ESR (Erythrocyte Sedimentation rate)	M 1 – 15 mm / hour F 1 – 20 mm / hour	1hr	1 x EDTA blood	2 hours	24/7	8 hours	Ampath Pretoria east/Lancet Pretoria east	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
F								
Fanconi PCR	N/A		2 x EDTA	2 weeks	Monday to Friday	7 days	Ampath NRL	Attention Dr Alant at Ampath NRL Genetics Department
Ferritin	M: 20 – 250 F: 10 – 120	ng/ml	1 x SST blood	2 hours	24/7	7 days	N/A	N/A
Female Hormone (FSH, Progesterone, oestradiol, LH)	Refer to individual test		1 x SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Fibrinogen	1.8-3.5	g/l	1 x Citrate blood	1 hour 4 hours (Morning rounds)	24/7	4 hours	N/A	N/A
FISH Kindly see Appendix 1 for a comprehensive list of probes offered	N/A	N/A	1 x Bone Marrow or Peripheral Blood sample in an EDTA/ Heparin Tube/ Tissue imprint	3-10 days	Monday to Friday (APL presentation Monday to Sunday)	48 hours if sorting needs to be done if not, no time limit	N/A	Alternatively, smears will be accepted if no other sample is available.
FFPE FISH Kindly see Appendix 1 for a comprehensive list of probes offered	N/A	N/A	3~5 um FFPE sections on a positively charged slide / FFPE Blocks	14 days	Monday to Friday	No time limit.	N/A	An H&E slide/ image with the area of interest ringed must be send with all FFPE sections/blocks. Also submit the IHC score where relevant
Full blood count (FBC)	N/A		1 x EDTA blood	1 hour	24/7	8 hours	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Fungitell	0.0-59.0	pg/ml	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	Test cannot be added. A rebleed is required if test is added.
Flowcytometry Diagnostic and MRD for: Myeloma B-ALL AML Mature B T-ALL Screening Panel Mature – T Mast Cell	N/A	%	2 x EDTA/ Heparin PB/ Bone marrow/ CSF Sample/ FNA Sample	48 hours (Diag) 120 hours (MRD)	Monday to Friday	72 hours	N/A	Need to reach the laboratory preferably within 24 hours after collection but no later than 72 hours. Transport CSF in 200ul transfix on ice (Arrange with laboratory if transfix is required.)
Flowcytometry PNH Panel	N/A	%	2 x EDTA/ Heparin PB only	48 hours	Monday to Friday	72 hours	N/A	Need to reach the laboratory preferably within 24 hours after collection but no later than 72 hours.
Flowcytometry Blast Clearance	N/A	%	1 x EDTA/ Heparin PB only	5 Days	24/7	72 hours	N/A	Sample on day 1 of chemo and day 4 post chemo.
FLT3 Mutational Analysis (ITD and D835Y)	NA	%	2 x EDTA, Extracted DNA (50ul of 5ng/ul)	3 Days	Monday to Friday	7 Days	NA	NA

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Folate (Folic Acid) RBC	317 – 1894	nmol/l	1 x EDTA blood	24 hours	24/7	7 days	Ampath NRL Lancet Pencardia/ Pathcare Vermaak	N/A
Folate (Folic Acid) serum	10.0 – 45.1	nmol/l	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Free T3 (Triiodothyronine)	3.5 – 5.4	pmol/l	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Free T4 (Thyroxine)	7.6 – 16.1	pmol/l	1 x SST blood	24 hours	24/7	7 days	N/A	N/A
FSH	Males: 1.27 - 19.26 Females: Mid-Follicular Phase: 3.85 - 8.78 Mid-Cycle Peak: 4.54 - 22.51 Mid-Luteal Phase: 1.79 - 5.12 Postmenopausal: 16.74 - 113.59	IU/L	1 x SST blood	2 hours	24/7	7 days	N/A	N/A
G								
G6PD	N/A	N/A	1 x EDTA blood	24 hours	24/7	2 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
GGT (Gamma glutamyl transferases)	< 60	U/l	1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Random Glucose	1Y-108Y :3.3-7.8	mmol/l	1 x Fluoride/1 x SST	1 hour	24/7	8 hours on Fluoride 2 hours on SST	N/A	N/A
Fasting Glucose	0D-<1D:2.2-3.3 1D-<1Y :2.8-4.4 1Y-<18Y :3.3-5.6 18Y-<61Y :4.1-5.9 61Y-90Y :4.6-6.4 >90Y :4.2-6.7							
Growth Hormone	M 0 – 0.97 F 0.01 – 3.61	µg/l	1 x SST blood	48 hours	24/7	7 days	Ampath NRL	N/A
H								
Haptoglobin	0.3-20	g/l	1 x SST blood	24 hours	24/7	7 days	Ampath/Lancet PTA East/ Pathcare Vermaak	N/A
HbA1c	4.3 – 6.1	%	1 x EDTA blood	24 hours	24/7	8 hours	Ampath/Lancet PTA East/ Pathcare Vermaak	N/A
Haemochromatosis PCR	N/A	N/A	1 x EDTA blood	7 days	Monday to Friday	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
HDL-cholesterol	≥1.55	mmol/l	1 x SST/Barricor blood	2 hours 5 hours (Morning rounds)	24/7	7 days	N/A	Patient should be fasting for 10-12hrs before sample collection.
Hepatitis Ab IgM IgG	N/A	IU/ml	1 x SST blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Hepatitis B group	N/A	IU/ml	1 x SST blood	72 hours	24/7	7 days	Ampath NRL Lancet Pencardia/ Pathcare Vermaak	N/A
Hepatitis B viral load	N/A	IU/ml	1 x SST blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Hepatitis C	N/A	IU/ml	1 x SST blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
HIV	N/A	IU/ml	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	Test cannot be added. Always collect a new sample.
Homocysteine	Adults < 15 Elderly <20	umol/l	1 x heparin blood	24 hours	24/7	72 hours	Ampath NRL	N/A
I								
Immune monitoring	N/A	N/A	1 x EDTA blood	24 hours	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Immunoglobulins: IgA, IgM, IgG, IgE	IgA: 0.70-4.00 IgM:0.40-2.30 IgG:7.00-160.00 IgE:0.00-160.00	g/l IU/ml	1 x SST blood	2 hours	24/7	7 days	N/A	N/A
INR (Refer to PT)	N/A	Ratio	1 x Citrate blood	1 hour	24/7	4 hours	N/A	N/A
Iron	Male: 12.5 – 32.2 Female:10.7 – 32.2	umol/l	1 x SST blood/ 1 x Barricor blood	2 hours 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
J								
JAK2 V617F PCR	N/A	N/A	2 x EDTA blood	7 days	Monday to Friday	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
K								
Karyotyping (Refer to Chromosome Analysis)	N/A	N/A	1 x Bone Marrow or Peripheral blood in Sodium Heparin (>20% Blast if Peripheral Blood)	30 Days	Monday to Friday	48 hours	N/A	Need to reach the laboratory preferably within 24 hours after collection but no later than 48 hours.
L								
Lactate dehydrogenase (LDH)	100 – 250	U/l	1 x SST/Barricor blood	2 hours 5 hours (Morning rounds)	24/7	7 days	N/A	No hemolysis

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
LDL- cholesterol	2.6-3.3	mmol/l	1 x SST/Barricor blood	2 hours 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Lipase	22 – 51	U/l	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
LH	Males: 1.24-8.62 Females Mid-Follicular Phase: 2.12-10.89 Mid-Cycle Peak: 19.18-103.03 Mid-Luteal Phase: 1.20-12.86 Postmenopausal: 10.87-58.64	IU/l	1 x SST blood	2 Hours	24/7	7 days	N/A	N/A
Lymphocyte subsets	N/A	N/A	1 x EDTA blood	24 hours	24/7	7 days	N/A	N/A
M								
Magnesium	0D-<5M:0.62-0.91 5M-<6Y:0.70-0.95 6Y-<12Y:0.70-0.86 12Y-<20Y:0.70-0.91 20Y-61Y:0.66-1.07 61Y-90Y :0.66-0.99 >90Y :0.70-0.95	mmol/l	1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
Manual differential count	N/A	N/A	1 x EDTA blood	24 hours	24/7	8 hours	N/A	N/A
Methotrexate	N/A	umol/l	1 x EDTA	24 hours	24/7	48 hours	Lancet Pencardia	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
NPM1 Mutational Analysis	NA	%	2 x EDTA, Extracted DNA (50ul of 5ng/ul)	3 Days	Monday to Friday	7 Days	NA	NA
Myeloma Profile (FBC, UKE, Ca, CRP, LFT+LD, UA, IgA, IgG, IgM, B2M) (QPE)	Refer to individual test		3 x SST blood	2 hours 5 hours (Morning rounds) 48 hours	24/7	8hrs 48hrs	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Myoglobin	M: 17 – 106 F: 14 – 66	ug/l	1 x SST	2 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
N								
NGS ALL	N/A	VAF	1 x EDTA blood or bone marrow	30 days	Monday to Friday	72 hours	N/A	N/A
NGS AML MRD	N/A	VAF	1 x EDTA blood or bone marrow	14 days	Monday to Friday	72 hours	N/A	N/A
NGS BrCo panel	N/A	VAF	1 x EDTA blood or saliva	30 days	Monday to Friday	7 days	N/A	N/A
NGS HLA typing	N/A	N/A	1 x EDTA peripheral blood/ 3 x buccal swabs/ 1 x saliva kit	14 days	Monday to Friday	7 days	N/A	N/A
NGS IGHV	N/A	VAF	1 x EDTA blood or bone marrow, sorted cells	30 days	Monday to Friday	7 days	N/A	N/A
NGS Lymphoma panel	N/A	VAF	1 x EDTA blood or bone marrow	30 days	Monday to Friday	72 hours	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
NGS Myeloid panel	N/A	VAF	1 x EDTA blood or bone marrow	14 days	Monday to Friday	72 hours	N/A	N/A
NGS Precision	N/A	VAF	FFPE, biopsy, plasma	30 days	Monday to Friday	1 year	Ampath NRL	N/A
NGS TP53	N/A	VAF	1 x EDTA blood or bone marrow, sorted cells	30 days	Monday to Friday	7 days	N/A	N/A
O								
Oestradiol	M 95-223 F 77 – 921	pmol/l	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Penciaardia/ Pathcare Vermaak	N/A
Osmolality	275 – 295	mOsm/kg	1x SST 5 ml urine	2 hours	24/7	24 hours	Ampath NRL/ Lancet Penciaardia/ Pathcare Vermaak	N/A
P								
Partial Thromboplastin Time (PTT)	22-30.7	sec	1 x Citrate blood	1 hour 4 hours (Morning rounds)	24/7	4 hours	N/A	N/A
PCR (Polymerase Chain Reaction)	Refer to Specific Tests				Monday to Friday			
Philadelphia Chromosome: PCR / FISH / Chromosome Studies	Refer to specific tests				Monday to Friday			

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Phosphate (PO4)	0D-<10D:1.45-2.91 10D-<3Y:1.29-2.10 3Y-<10Y:1.03-1.87 10Y-<16Y:1.07-1.74 16Y-<60Y :0.78-1.42 M(60Y-89Y) :0.74-1.20 F(60Y-89Y) :0.90-1.26 M(>89Y) :0.71-1.26 F(>89Y) :0.81-1.36	mmol/L	1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	N/A	N/A	N/A
Platelet aggregation	N/A	N/A	6x citrate blood	N/A	24/7	N/A	Ampath NRL	Complete N/A the clotting profile form.
Platelet Flowcytometry	N/A	%	2 x EDTA blood	24 hours	24/7	48 hours	Ampath NRL	N/A
PML::RARA (PCR)	N/A	N/A	2 x EDTA blood	2 weeks	Monday to Friday	3 days	Ampath NRL	N/A
PNH (Flow cytometry)	N/A	%	1 x EDTA blood	24 hours	Monday to Friday	7 days	N/A	N/A
Potassium	0D-<1M:3.7-5.9 1M-<1Y:4.1-5.3 1Y-<12Y:3.4-4.7 12Y-108Y:3.5-5.1	mmol/L	1 x Barricor blood 1 x SST blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	FL24/7	7 days	N/A	

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Post-transplant screening FBC, UEC, LFT+LDH, CRP Chimerism-monitoring CMV viral load	Refer to individual test. Refer to individual test.		1 x SST/Barricor blood 4 x EDTA 1 x EDTA	1 hour 5 hours (Morning rounds)	24/7	7 days 4 days 72 hours	N/A	Week 6 + Week 12 Weekly for the first 14 weeks post-transplant on all allogeneic transplants (Only if requested by the physician on autologous transplants)
Pre-transplant screening FBC + retic, UEC, CMP, LFT+LDH, CRP, Uric Acid INR+ PTT (if required/J-line) Fibrinogen, Thrombin time, D-dimer ABO + Rh typing Malaria screen (smear and Ag) – or PCR and Ag Anti-A or B titre (if blood group mismatch) Patient HLA antibodies (if HLA mismatch/ haplo-identical) BHCG - qualitative	Refer to individual tests	N/A	5 x EDTA blood 1 x citrate blood 7 x SST blood 1 x Blood culture 1 x Swab 1 x Urine	Refer to individual tests	24/7	Refer to individual tests	N/A Some tests: Ampath NRL/ Lancet Penciaardia Pathcare Vermaak	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Iron studies (iron, transferrin, transferrin saturation, ferritin) HIV p24 + Ab serology Hep A IgM/IgG Hep B sAb/sAg/cAb Hep C IgM and IgG CMV IgM/IgG EBV IgM/IgG/EBNA Toxoplasmosis IgM/IgG RPR / Treponema serology QPE IgG/IgM/IgA HTLV1 – (if required) SFLC ratio (if Myeloma) BLPAED (if required clinically) Rectal screen (VIM, CRE PCR only for autologous donors – done at admission and prior to transplant)								

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Pre-transplant screening (continues) • Urine – (MCS & prot if required clinically) • Haemoglobino pathy – (if history requires)	Refer to individual tests	N/A	5 x EDTA blood 1 x citrate blood 7 x SST blood 1 x Blood culture 1 x Swab 1 x Urine	Refer to individual tests	24/7	Refer to individual tests	N/A Some tests: Ampath NRL/ Lancet Pencardia Pathcare Vermaak	N/A
Procalcitonin (PCT)	0.0 – 0.05	ng/ml	1 x SST blood	2 hours 5 hours (Morning rounds)	24/7	48 hours	N/A	N/A
17-hydroxy – Progesterone	M 1.9 – 6.52 nmol/l F: Follicular phase 0.97 – 4.45 or ovarian Luteal phase 0.76 – 8.79 Oral contraceptive 0.60 – 5.75 Post-menopausal 0.56 – 2.15	nmol/l	1 x SST blood	24 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Progesterone	Males: 0.3-5.1 Females (Non pregnant) Mid-follicular phase: 0.8-3.8 Mid-luteal phase: 12.9-46.3 Post-menopausal: <0.2-1.9 Females (Pregnant): First trimester: 11.8-126.6 Second trimester: 48.4-113.1	nmol/l	1 x SST blood	2hours	24/7	7 days	N/A	N/A
Prolactin	M ≥18 years 3-13 F 18 – 49 years 3 – 27 ≥50 years 3 – 20	µg/l	1 x SST blood	48 hours	24/7	7 days	Ampath NRL / Lancet Pencardia Pathcare Vermaak	N/A
Protein S	M 60 – 140 F 70 – 140	%	1 x Citrate blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Protein C	70 – 140	%	1 x Citrate blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Protein Electrophoresis	N/A	N/A	1 x SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Prothrombin Time (PT)	9-11.2	sec	1 x Citrate blood	1 hour 4 hours (Morning rounds)	24/7	4 hours	N/A	N/A
Prostate Specific Antigen (PSA)	0 – 4	ng/ml	1 x SST	2 Hours	24/7	7 days	N/A	N/A
R								
Reticulocytes (retics)	0.25 – 0.5 50 - 100	% 10*6/ul	1 x EDTA blood	1 hour	24/7	4 hours	N/A	N/A
Rheumatoid Factor	0.0-15.9	IU/ml	1 x SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
S								
SARS-CoV2 PCR	N/A	N/A	1 x respiratory swab	24 hours	Monday to Friday	48 hours	Ampath NRL	N/A
Sensitive Estradiol	Early Follicular: 308-567 Mid Follicular: 350-510 Ovulatory Peak: 1574-2283 Mid Luteal: 797-1024 Post-Menopausal: 73-110	pmol/l	1x SST	2 hours	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
SHBG	Males 20-50 years: 13.3-89.5 Females 20-46 years: 18.2-135.5 47-91 years: 16.8-125.2	nmol/l	1 x SST blood	2hours	24/7	7 days	N/A	N/A
Sodium	OD-<1M:133-146 1M-<1Y:139-146 1Y-<12Y:138-145 12Y-<90Y:136-145 90Y-108Y:132-146	mmol/L	1 x Barricor blood 1 x SST blood	BEN/Wilg 2 hours PE 1 hour 5 hours (Morning rounds)	24/7	7 days	N/A	N/A
T								
Tacrolimus	3-12	ng/ml	1 x EDTA blood	24hr	24/7	24 hours	Ampath NRL	N/A
TB culture (bone marrow)	N/A		1 x heparin	7 days	24/7	24 hours	Ampath NRL	N/A
Total Testosterone	Males: 9.0 – 35 Males 20-50 years: 4.0-15.5 Females 20-46 years: 0.13-1.30 47-91 years: 0.043-0.763	nmol/l	1 x SST blood	2 hours	24/7	48 hours	N/A	N/A
Free Testosterone (includes SHBG)								
Thrombin Time	14-20	sec	1 x Citrate blood	1 hour 4 hours (Morning rounds)	24/7	4 hours	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Thyroid Abs Anti-thyroglobulin, Anti-thyroperoxidase, TSH receptor Abs	<116 <35 <1.75	IU/ml	1 x SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	No hemolysis or lipaemia
Thyroid Abs Anti-thyroglobulin, Anti-thyroperoxidase, TSH receptor Abs	<116 <35 <1.75	IU/ml	1 x SST blood	48 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	No hemolysis or lipaemia
Thyroid Stimulating Hormone	0.4-3.5	IU/L	1 x SST blood	24 hours	24/7	7 days	N/A	N/A
TORCH (Toxoplasma, CMV, Rubella, Herpes Simplex, RPR, TPHA)	Refer to the individual analytes		1 x SST blood	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
TPHA (Treponema Pallidum Haemagglutination)	N/A	N/A	1 x SST blood 1 x CSF	72 hours	24/7	7 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Transferrin	0 - 3 months: 1.30 - 2.75 3 months - 10 years: 2.03 - 3.60 > 10 years: 2.00 - 3.60	g/l	1 x SST/Barricor blood	2 hours 5 hours (Morning rounds)	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Triglycerides	0.50-<1.7	mmol/l	1 x SST blood	2 hours 5 hours (Morning rounds)	24/7	7days	N/A	N/A
Trop I	0 – 14	ng/l	1 x SST blood	2 hours	24/7	6 hours	Ampath/Lancet Pretoria east Pathcare Vermaak	N/A
Trop T	0 – 14	ng/l	1 x SST blood	2 hours	24/7	6 hours	Ampath Pretoria east /Lancet Pretoria east Pathcare Vermaak	N/A
Tumor lysis Profile 6 hourly: FBC, Na, K+, Urea, Creat, Ca, PO4 Daily: FBC, UCE, Uric acid, CMP, LFT + LDH	Refer to the individual analytes	N/A	1 x EDTA blood 1 x SST/Barricor Blood 1 x Citrate blood	1 hour	24/7	7 days	N/A	N/A
U								
UEC (Urea, creatinine, electrolytes)	Refer to the individual tests		1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Urea	M(0D-<1M):1.4-4.3 F(0D-<1M):1.1-6.1 M(1M-<1Y):0.7-4.6 F(1M-<1Y):1.4-5.0 M(1Y-<4Y):1.1-4.3 F(1Y-<4Y):1.1-5.0 M(4Y-<7Y):1.1-5.7 F(4Y-<7Y):1.4-5.0 M/F(7Y-<10Y) :1.14-5.7 M(10Y-<13Y):1.8-6.4 F(10Y-<13Y):1.8-5.7 M(13Y-<16Y):2.5-6.4 F(13Y-<16Y):1.4-5.4 M(16Y-<18Y):1.8-7.1 F(16Y-<18Y):1.4-5.4 M/F(18Y-<61Y) :2.1-7.1 M/F(61Y-108Y) :2.9-8.2	mmol/l	1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour	24/7	7 days	N/A	N/A
Uric acid	F: 12Y-108Y:0.15-0.35 M:12Y-108Y:0.2-0.42	mmol/l	1 x SST/Barricor blood	BEN/Wilg 2 hours PE 1 hour	24/7	7 days	N/A	N/A

TEST	REF. RANGES	UNITS	SPECIMEN	*TAT	Test Availability	STABILITY	REFERRAL LAB	SPECIAL INSTRUCTION
Urine chemistry (Na, K, Urea, Creat, Prot, Glu)	Refer to the individual analytes	mmol/l	20 ml random urine	24 hours	24/7	2 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	No preservatives
Urine MC&S	N/A	N/A	20 ml random urine in sterile specimen bottle	Minimum :3 days	24/7	2 hours	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	No preservatives
V								
Viral load HIV-1	N/A	N/A	1 X EDTA blood	72 hours	24/7	90 days	Ampath NRL/ Lancet Pencardia/ Pathcare Vermaak	N/A
Vitamin B 12	107-443	pmol/l	1 x SST blood	2 hours	24/7	7 days	N/A	N/A
25 (OH) Vitamin D	Deficiency: <20 Insufficiency: 20 to <30 Sufficiency: 30-100 Potential toxicity: >100	ng/ml	1 x SST blood	2 hours	24/7	7 days	N/A	N/A

3.1 SAMPLE STORAGE

- 3.1.1 All samples can be stored at RT pre-processing unless otherwise specified.
- 3.1.2 Specimen stored at 2-8°C after testing if not otherwise indicated, refer to SOP-5004 and specific Assay SOPs for more detailed information where relevant.

3.2 SAMPLE TRANSPORTATION.

- 3.2.1 Samples are transported at room temperature unless otherwise indicated.
- 3.2.2 Samples collected in the hospital wards are transported at room temperature as per sample collection protocol except for analytes indicated otherwise above.
- 3.2.3 Samples transported to referral labs (AMPATH/LANCET) are collected by their couriers respectively.
- 3.2.4 Samples transported between Oncolab sites are packed in the courier bag with 1 x ice pack to assist samples to stay at room temperature during transport.

3.3 TURNAROUND TIME (*)

- 3.3.1 TAT refers to the turnaround time specimen is received in the laboratory to the time the results are issued.
- 3.3.2 Turnaround time may be increased in case of reflex tests based on patients results, this may also be relevant for tests where we batch samples.
- 3.3.3 Turnaround time for Ward 2 and Ward 20 between 03:00-08:00 is 5 hours.
- 3.3.4 When the TAT is affected by either reagent stock outs, equipment downtime or critical staff shortages, the laboratory will inform the requesting clinicians as per SOP-5046, however should this be due to additional work-up or complexity of the cases, usually related to the reference laboratory, the clinicians may not always be notified.

APPENDIX A: Fluorescence in situ hybridization (FISH) Probe list

	Name	Probes	Chromosomes	Fluorochrome labelled	Suppliers	Probe Design
1.	7q31	LSI D7S486/CEP7	7q31/CEP7	(D7S486)(CEP7)	Vysis	Deletion
	7q31	XL del(7)(q22q31)	CEP7,KMT2E,MET	(CEP7,KMT2E,MET)	Metasystems	Deletion
2.	5q31/5q33	LSI CSF1R/D5523,D55721	CSF1R/D5523,D55721	(CSF1R)(D5523,D55721)	Vysis	Deletion
	5q31/5q33	XL 5q31/5q33	CDC25C/EGR1,RPS14	(CDC25C,EGR1/RPS14)	Metasystems	Deletion
	5q31	XL 5q31	D5S1518E,EGR1	(D5S1518E,EGR1)	Metasystems	Deletion
3.	Trisomy 8	XCE 8 Orange	Trisomy 8	(XCE8)	Metasystems	Trisomy
4.	20q12	LSI D20S108	20q12	D20S108	Vysis	Deletion
	20q12/20qter	XL 20q12/20qter plus	20q12/20qter	(20q12)(20q13.3)	Metasystems	Deletion
5.	CEP X/Y	XCE X/Yqh	X/Y	(CEPX)(Yq12)	Metasystems	XY
6.	t(15;17)	XL t(15;17) DF	(15q24)(17q21.2-21.2)	(PML)(RARA)	Metasystems	Dual fusion
7.	t(9;22)	XL BCR/ABL1 plus	t(9;22)(q34.1;q11.2)	(ABL1)(BCR)	Metasystems	Dual fusion
8.	11q23 (MLL)	XL MLL DC BA	11q23.3	(5'KMT2A)(3'KMT2A)	Metasystems	Break apart
9.	inv16 (CBFB)	XL CBFB	16q21-22	(5'CBFB)(3'CBFB)	Metasystems	Break apart
10.	t(8;21)	XL t(8;21) plus	t(8;21)(q21.3-22.1;q22.1)	(RUNX1T1)(RUNX1)	Metasystems	Dual fusion
11.	t(1;19)	LSI TCF3/PBX1 DC DF	t(1;19)(q23;p13.3)	(TCF3)(PBX1)	Vysis	Dual fusion
12.	8q24 (MYC)	XL MYC BA	8q24.21	(5'MYC)(3'MYC)	Metasystems	Break apart
13.	18q21 (BCL2)	XL BCL2 BA	18q21	(3'BCL2)(5'BCL2)	Metasystems	Break apart
14.	3q27 (BCL6)	XL BCL6 BA	3q27-28	(5'BCL6)(3'BCL6)	Metasystems	Break apart
15.	14q32 (IGH)	XL IGH BA	14q32.3	(5'IGH)(3'IGH)	Metasystems	Break apart
16.	6p25 (IRF4)	XL IRF4(6p25) BA	6p25.3	(5'IRF4)(3'IRF4)		Break apart
17.	2p23 (ALK)	XL ALK (2p23) BA	2p23	(5'ALK)(3'ALK)		Break apart
18.	17p13 (TP53)	XL TP53/NF1	(17q11.2)(17p13)	(NF1)(TP53)	Metasystems	Deletion
19.	13q14	XL DLEU/LAMP	(13q14.2)(13q34)	(DLEU)(LAMP)	Metasystems	Deletion
20.	1p32/1q21	XL CDKN2C/CKS1B	(1q21-22) (1p32.3)	(CKS1B)(CDKN2C)	Metasystems	Deletion/Amp
21.	t(4;14)	XL IGH/FGFR3 DF	t(4;14)(p16;q32)	(FGFR3)(IGH)	Metasystems	Dual fusion
22.	t(11;14)	XL t(11;14) MYEOV/IGH DF	t(11;14)(q13;q32)	(MYEOV/CCND1)(IGH)	Metasystems	Dual fusion
23.	t(14;16)	XL t(14;16) IGH/MAF DF	t(14;16)(q32.3;q23)	(IGH)(MAF)	Metasystems	Dual fusion
24.	t(14;20)	XL t(14;20) IGH/MAFB DF	(14q32.3)(20q12)	(IGH)(MAFB)	Metasystems	Dual fusion
25.	Trisomy 12	XCE 12 Orange	Trisomy 12	(XCE12)	Metasystems	Trisomy
26.	11q22 (ATM)	XL ATM/11cen	(11p11.11-q11)(11q22.3)	(XCE11)(ATM)	Metasystems	Deletion
27.	11q13 (CCND1)	XL CCND1	11q13	(5'CCND1)(3'CCDN1)	Metasystems	Break apart
28.	t(14;18)	XL t(14;18) IGH/BCL2 DF	t(14;18)(q32.3;q21.3)	(IGH)(BCL2)	Metasystems	Dual fusion
29.	t(8;14)	XL t(8;14) MYC/IGH DF 8cen	t(8;14)(q24;q32)	(CEP8)(MYC)(IGH)	Metasystems	Dual fusion
30.	inv3	XL MECOM 3q26	3q26	(3'MECOM,5'MECOM)	Metasystems	Dual fusion
31.	t(12;21)	XL t(12;21) ETV6/RUNX1 DF	t(12;21)(p13.2;q22.1)	(ETV6)(RUNX1)	Metasystems	Translocation
32.	18q21 (MALT1)	MALT1 Break apart	18q21.3	(5'MALT1)(3'MALT1)	Vysis	Break apart
	18q21 (MALT1)	XL MALT1 BA	18q21.3	(5'MALT1)(3'MALT1)	Metasystems	Break apart
33.	t(6;9)	XL t(6;9) DEKNUP14	t(6;9)(p22;q34)	(DEK)(NUP214)	Metasystems	Dual fusion
34.	8p11.2 (FGFR1)	XL FGFR1	8p11.2	(5'FGFR1)(3'FGFR1)	Metasystems	Break apart
35.	4q12 (PDGFRA)	XL 4q12	4q12	(FIP111)(CHIC2)(PDGFRA)	Metasystems	Translocation/
36.	5q32 (PDGFRB)	XL 5q32 PDGFRB BA	5q32-33.1	(5'PDGFRB)(3'PDGFRB)	Metasystems	Break apart
37.	17q21 (RARA)	XL RARA BA	17q21	(5'RARA)(3'RARA)	Metasystems	Break apart
38.	20q12/CEP8	XL 20q12/20qter/8cen plus	20q21/Cep8	(8cen,D20S108,RH74808)	Metasystems	Deletion/Trisomy
39.	ERBB2	XL ERBB2 (HER2/NEU) amp	17q12/Cep17	(CEP17)(ERBB2)	Metasystems	Amplification
	ERBB2	ERBB2 (17q12/SE17)	17q12/Cep17	(CEP17)(ERBB2)	Kreatech	Amplification
40.	TP63	TP63 Break apart/3qtel	3q28/3q29	(3' TP63)(5'TP63)(3q29)	Cytocell	Break apart
41.	NMYC	XL MYCN Amp	2p24/2q23	(2p24)(2q23)	Metasystems	Amplification

4. SOP 5005 RECEIVING OF SPECIMEN

4.1 CRITERIA FOR REJECTING SPECIMEN.

- 4.1.1 Specimen not accompanied by a request form.
- 4.1.2 Name on the request form and on the tube does not correlate.
- 4.1.3 Incorrect tube collected for the test requested.
- 4.1.4 Inadequate specimen volume as per individual tests.
- 4.1.5 Improper transport handling e.g., specimen not kept on ice, where applicable.
- 4.1.6 Samples where the stability was compromised.
- 4.1.7 On the LIS, cancel the test requested and add a reason for cancellation as a note, refer to SOP-5005 and SOP-4012.

5. PHLEBOTOMY PROCEDURE

5.1 For collection of peripheral blood, the phlebotomy procedure of the collection site will be followed.

5.1.1 Completion of a request form

5.1.1.1 The following information is mandatory for data capturing, processing, and reporting of results on laboratory specimens:

- 5.1.1.1.1 Patient name and surname, gender, age and date of birth and identification (ID) number/passport number.
To ensure that the laboratory data is matched to the correct patient and that appropriate age and gender adjusted reference intervals are supplied.
- 5.1.1.1.2 If the patient is a donor, Oncolab Transplant request form should be completed, and donor details completed accordingly.
- 5.1.1.1.3 The patient's preferred referral laboratory must be confirmed when there are referred tests requested.
Refer to FORM 1: SOP 3008 User's Manual and Advisories for a list of referred tests and laboratories.

- 5.1.1.1.4 Name or unique identifier of the requesting clinician to ensure that the laboratory results are sent to the appropriate clinician.
- 5.1.1.1.5 Location where the sample was collected, e.g., Ward or doctor's rooms. Hospital number for hospitalised patients. Hospital sticker should be sufficient.
- 5.1.1.1.6 Date and time of sample collection.
- 5.1.1.1.7 Name of the person or phlebotomist collecting the specimens.
- 5.1.1.1.8 Primary specimen type and number of specimens collected.
- 5.1.1.1.9 Anatomical site of where the specimen was collected if applicable.
- 5.1.1.1.10 Concise description of the clinical problem/diagnosis.
- 5.1.1.1.11 Name or list of tests to be performed.
- 5.1.1.1.12 Account details are mandatory for billing purposes.
- 5.1.1.1.13 Patient signature is important as it is proof of consent to commence with the requested test and the billing thereof. HIV consent form of the relevant referral laboratory is mandatory if HIV test is requested.
- 5.1.1.1.14 Patient identification can be done by various methods e.g., verbal, wrist band.

5.1.2 Identify the patient

- 5.1.2.1 Approach the patient in a calm and friendly manner and introduce yourself to the patient.
- 5.1.2.2 Ask to state their full name (do not ask if the name is e.g., Mr John Doe as they might respond incorrectly to a leading question) _and check that it matches the information on the request form. If there is a patient in the ward with the similar surname, ask the patient to confirm their date of birth.
- 5.1.2.3 Record on the request for how you identified the patient e.g., verbal, wrist band, Sr in the ward. Sign next to this record.
- 5.1.2.4 Check the request form for requested tests and any specific requirements.
- 5.1.2.5 Make the patient comfortable and gain his/her co-operation.

- 5.1.2.6 Discuss the test/s and procedure to be performed and obtain signed consent. Ensure that the patient has understood the procedure.
- 5.1.2.7 Wash hands with soap and water and dry with paper towels OR clean with alcohol rub.
- 5.1.2.8 Put on well-fitting, non-sterile gloves.
- 5.1.2.9 Add appropriate PPE for all areas, i.e., masks, gowns etc.
- 5.1.2.10 Patients who are isolated to be taken last in ward 20 and elsewhere.

5.1.3 Order of draw

- 5.1.3.1 Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes.
- 5.1.3.2 The recommended order of draw for plastic vacutainer tubes is describe in table 10:

Table 10. Order of draw – and number of inversions, minimum volume

Order	Type of tube	Additive	Mode of action	Uses
1	Blood culture bottle 	Broth mixture	Preserve the viability of microorganisms	Microbiology
2	Non-additive tube (red or tan top) 	None		
3	Coagulation tube (light blue top) 	Sodium citrate	Forms calcium salts to remove calcium	Coagulation tests (PT, PTT), requires a full draw

4	Clot activator (red top) 	Clot activator	Allow the blood to clot where after serum is separated by centrifugation	Chemistry, immunology, serology, and blood bank (crossmatch)
5	SST (gold top). Or yellow top 	Gel at the bottom of the tube	Separate blood from serum after centrifugation	Chemistry, immunology, and serology.
6	Sodium heparin (dark green top) 	Sodium heparin or lithium heparin	Inactivate thrombin and thromboplastin	Ammonia level or for lithium level use sodium heparin
7	Barricor (light green top) 	Lithium heparin	Inactivate thrombin and thromboplastin	Chemistry
8	EDTA (purple top) 	EDTA	Forms calcium salts to remove calcium	Haematology
9	ACD/ACDA/ACDB (pale yellow top) 	Acid Citrate dextrose	Complement inactivation	HLA tissue typing, paternity testing, DNA studies

10	Oxalate/fluoride (light grey top) 	Sodium fluoride and potassium oxalate	Antiglycolytic agent to preserve glucose up to five days	Glucose
----	---	---	--	---------

5.1.3.3 NOTE: Gently invert the tubes with additives to mix thoroughly. Do not mix vigorously.

5.1.3.4 Inadequate or incorrect method of mixing can result in the following:

5.1.3.4.1 Vigorous mixing can cause foaming and haemolysis of the sample.

5.1.3.4.2 Insufficient and delayed mixing in plasma tubes may result in clotting and potentially incorrect results.

5.1.4 Patient -collected samples

5.1.4.1 There are three standard types of specimen collection that patients may be asked to provide i.e., urine, sputum, and saliva.

5.1.4.2 Explain to the patient the following information for each specimen collection:

5.1.4.2.1 Urine

- Obtain a 50ml dry, sterile specimen container.
- Collect the urine sample in the container and ensure the container is screwed tight to avoid leakage during transportation.
- Strict aseptic techniques should be followed for urine samples collected for microbiology testing to minimise contamination as the recovery of contaminants or normal microbial flora will be misleading and resulting in appropriate patient management. This includes washing hands before taking the sample and not touching the inside of collection container.

- Midstream urine should be collected to decrease bacterial contamination risk. This means that the patient should first pass a small amount of urine into the toilet and then start collecting the sample into the container. After a small volume is collected (no need to fill the container to the brim) the rest of the urine can be passed into the toilet.
- Label the specimen with patient name and date of birth.
- Transport the urine specimen to the referral lab within 2 hours of collection.

5.1.4.2.2 Sputum

- Rinse the mouth with water to prevent contamination with food particles, mouth wash and oral drugs.
- Take a deep breath and exhale two times.
- On the third time, cough deeply from your chest.
- Place the open sterile specimen bottle close to the mouth to collect the sputum.
- Screw the lid on tightly to avoid leakage during transportation.

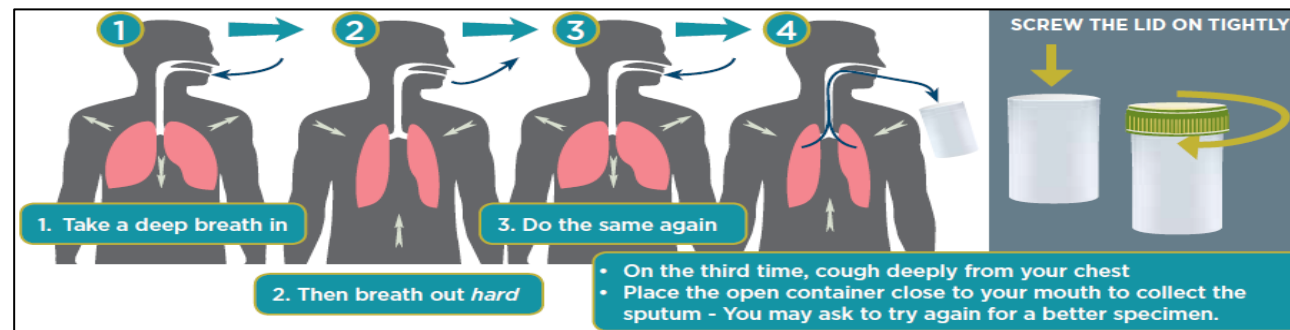
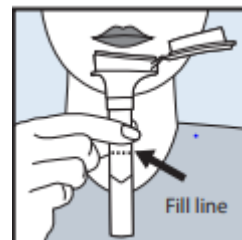


Figure 1: Sputum collection diagram

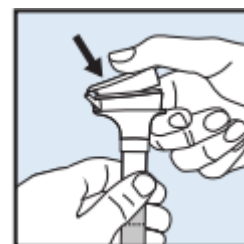
5.1.4.2.3 Saliva (go DNA kit)

- go DNA kit is used for the collection of human DNA from saliva samples.

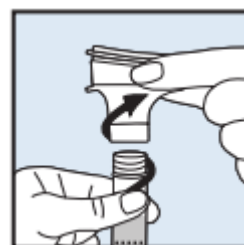
- Spit into the funnel until the amount of liquid saliva (not bubbles) reach the fill line as shown in below:



- Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown below) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the saliva. Make sure the lid is closed tightly.



- Hold the tube upright. Unscrew the funnel from the tube.



- Use the small cap to close the tube tightly.
- Shake the capped tube for 5 seconds. Discard the funnel.

5.1.4.2.4 Buccal swabs

- Rinse the mouth with water to prevent contamination with food particles, mouth wash and oral drugs.
- Use 3 swabs.
- Hold the handle of a swab, place in mouth and rub the swab using a twisting motion for 10 seconds on the inside of the cheek.
- Repeat using the same swab on the inside of the other cheek.
- Repeat with the other 2 swabs.

5.1.5 Safety procedures

- 5.1.5.1 It is important to always follow safety procedures.
- 5.1.5.2 Factors that increase the risk of haemolysis include:
 - 5.1.5.3 Use of a needle of too small a gauge (23 or under), or too large a gauge for the vessel.
 - 5.1.5.4 Pressing the syringe plunger to force the blood into a tube, thus increasing the shear force on the blood cells.
 - 5.1.5.5 Drawing blood specimens from an intravenous or central line.
 - 5.1.5.6 Underfilling a tube so that the ratio of anticoagulant to blood is greater than 1:9.
 - 5.1.5.7 Mixing a tube too vigorously
 - 5.1.5.8 Failing to let alcohol or disinfectant dry.
 - 5.1.5.9 Using too large a syringe.
 - 5.1.5.10 Protect yourself and follow universal precautions:
 - 5.1.5.10.1 Wear gloves and lab coat when handling blood / body fluids.
 - 5.1.5.10.2 Change gloves after each patient or when contaminated.
 - 5.1.5.10.3 Wash hands frequently.
 - 5.1.5.10.4 Dispose of items in appropriate containers.

5.1.5.10.5 Dispose of the needle immediately after removal from the patient's vein. Use one hand to put the needle into the slot in the sharps container and twist it to remove the needle from the holder. Do not bend, break, or recap needles to avoid accidental needle stick injuries.

5.1.5.11 If you stick yourself with a contaminated needle:

5.1.5.11.1 Remove your gloves and dispose of them properly.

5.1.5.11.2 Squeeze puncture site to promote bleeding.

5.1.5.11.3 Wash the area well with soap and water.

5.1.5.11.4 Record the patient's name and ID number.

5.1.5.11.5 Follow Oncolab guidelines regarding PEP treatment and follow-up.

5.1.6 Protect the patient

5.1.6.1 Place blood collection equipment away from patients.

5.1.6.2 Practice hygiene for the patient's protection.

5.1.6.3 Change gloves between each patient and wash your hands frequently.

5.1.6.4 Always wear a clean lab coat.

5.1.6.5 Place the used tourniquets in a container with soap and water. Each shift is responsible for washing all tourniquets used during their shift.

5.1.7 Sample information

5.1.7.1 See Table 1 for the different tubes used for sample collection.

5.1.7.2 Include specific transport instructions as required.

5.1.7.3 Include specimen retention time and storage conditions.

5.1.7.4 Indicate acceptance and rejection criteria for primary samples.

5.1.8 Environmental and safety controls

- 5.1.8.1 All patient samples and reagents should be treated as potentially infectious and handled observing the usual safety precautions (do not ingest, do not inhale).
- 5.1.8.2 Wear appropriate PPE as when handling potentially infectious samples, including gloves and laboratory coats.
- 5.1.8.3 Dispose of used reagents and other contaminated disposable materials following procedures for potentially infectious products e.g., waste cardboard boxes with red bags.
- 5.1.8.4 State specific MSDS used e.g., Ethanol.
- 5.1.8.5 Indicate use of additional PPE and biosafety cabinet specific to test.

6. POPI ACT CONSENT DECLARATION

You hereby declare and confirm that you, as the person/entity/body/individual/company who is providing information and hereinafter collectively referred to as “the applicant”, do hereby irrevocably agree and understand that any/all information supplied or given to Oncolab Diagnostics (pty) Ltd hereinafter referred to as Oncolab, is done so in terms of this agreement and consent declaration.

(“FULL LEGAL COMPANY NAME OF THE APPLICANT”)

6.1 INTERPRETATION

6.1.1 In this Agreement, unless inconsistent with or otherwise indicated by the context –

- 6.1.1.1 “This Agreement” means the Agreement contained in this document.
- 6.1.1.2 “The Company” means Oncolab Diagnostics (Pty) Ltd. and includes its affiliated, holding, and subsidiary companies.
- 6.1.1.3 “Personal information” means personal information as defined in the Protection of Personal Information Act adopted by the Republic of South Africa on 26 November 2013 and includes but is not limited to:

- 6.1.1.3.1 Information relating to the race, gender, sex, pregnancy, marital status, national, ethnic, or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language, and birth of the person.
- 6.1.1.3.2 Information relating to the education or the medical, financial, criminal or employment history of the person as well as relatives.
- 6.1.1.3.3 Any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier, or other assignment to the person.
- 6.1.1.3.4 The biometric information of the person.
- 6.1.1.3.5 The personal opinions, views, or preferences of the person.
- 6.1.1.3.6 Correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence.
- 6.1.1.3.7 The views or opinions of another individual about the person.
- 6.1.1.3.8 The name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person.
- 6.1.1.3.9 Preferred working details, area of work, expertise areas, employment type, remuneration, expectations.
- 6.1.1.3.10 Identity document, curriculum vitae, qualifications, degrees, certificates etc.
- 6.1.1.4 “The effective date” means the date of which the applicant agreed to the terms and conditions.
- 6.1.1.5 “The parties” means the parties as described hereinabove.
- 6.1.1.6 “divulge” or “make use of” means to reveal, make known, disclose, divulge, make public, release, publicise, broadcast, communicate or correspond or any such other manners of divulging of any information.
- 6.1.1.7 “processing” means any operation or activity or any set of operations, whether by automatic means, concerning personal or any information, including but not limited to:

- 6.1.1.7.1 the collection, receipt, recording, organisation, collation, storage, updating or modification, retrieval, alteration, consultation, or use.
- 6.1.1.7.2 dissemination by means of transmission, distribution or making available in any other form; or
- 6.1.1.7.3 merging, linking, as well as restriction, degradation, erasure, or destruction of information.
- 6.1.1.8 **“POPI”** means the Protection of Personal Information Act adopted by the Republic of South Africa on 26 November 2013 and as amended from time to time.

6.2 WHEREAS IT IS AGREED THAT

- 6.2.1 All parties agree that they will comply with the Protection of Personal Information Act No. 4 of 2013, regulations and process all information or personal data in respect of the service being rendered in accordance with the said regulation and only for the purpose of providing services or the normal course of business which include providing such information to third parties in the vetting process set out in the agreement to provide services.
- 6.2.2 The company represents that any information provided to Oncolab Diagnostics (Pty) Ltd. hereunder is compliant with the POPIA, and adequate consents and approvals from the concerned data subjects if any, have been duly obtained in writing, if applicable under the POPIA. Proof of such consent, if required, shall be furnished by the Company.
- 6.2.3 The company, Oncolab staff, all the parties to this agreement and the Applicant and any subsequent party/parties to this agreement acknowledge and confirm that:
 - 6.2.3.1 One or more of the parties to this agreement, will possess and will continue to possess information that may be classified or deemed as private, confidential, or as personal information.
 - 6.2.3.2 Such information may be deemed as the private, confidential, or as personal information as far as it relates to any party to this agreement as well as any third person who may be directly or indirectly associated with this agreement.

- 6.2.4 Further it is acknowledged and agreed by all parties to this agreement, that such private, confidential, or as personal information may have value and such information may or may not be in the public domain.
- 6.2.5 By agreeing, all parties irrevocably agree to abide by the terms and conditions as set out in this agreement as well as you irrevocably agree and acknowledge that all information provided, whether personal or otherwise, may be used and processed by Oncolab Diagnostics and such use may include placing such information in the public domain.
- 6.2.6 Further it is specifically agreed that Oncolab Diagnostics will use its best endeavours and take all reasonable precautions to ensure that any information provided, is only used for the purposes it has been provided.
- 6.2.7 All parties acknowledge that they have read all the terms in this policy and that they understand and agree to be bound by the terms and conditions as set out in this agreement.
- 6.2.8 It is confirmed that by submitting information to Oncolab Diagnostics irrespective as to how such information is submitted, you consent to the collection, collation, processing, and storing of such information and the use and disclosure of such information in accordance with this policy.
- 6.2.9 The Company has the right to request access to all information held, update or deletion to such information, or withdraw this consent, in writing, using the prescribed forms available on request, at any time, bearing in mind that withdrawal may not be possible in certain instances without negatively affecting contractual relationships, or in terms of a regulatory requirement.
- 6.2.10 Such requests may be directed to the information officer at taniav@oncolab.co.za

Signed on this day the _____ of _____ 20____, at _____ in my capacity as _____, of the company.

Signature

Full name and surname

7. SOP-6002 FEEDBACK AND COMPLAINT PROCEDURE

- 7.1.1 It is the policy of Oncolab diagnostics to encourage feedback from its clients as this used for continual improvement of the quality management system.
- 7.1.2 All queries, concerns or complaints can be sent to oncoadmin@oncolab.co.za. A feedback and complaint procedure is in place that will be followed when received.
- 7.1.3 Oncolab undertakes to consider, investigate and act on all feedback received and, where possible, will communicate the outcome with the users.

7.2 SOP-6002 FORM 1: FEEDBACK AND COMPLAINTS REGISTER

☐ EXTERNAL	☐ INTERNAL
From Business site:	To Business site:
Raised against:	
Complaint ☐	Query ☐
Complaint recorded by:	Date:
Complaint reported by:	Date:
Complaint raised by:	Date:
Time frame for completion of investigation/ Due date:	
Brief explanation of the complaint/Query:	
Investigation:	
Root cause analysis: (Refer to Appendix 1 SOP-6002 for possible causes)	
Signed by Investigator:	
Date:	

Figure 2: Feedback and complaint register

Referred for resolution to:	Date:
Signed:	
Resolution/Corrective Action/Immediate Action: (Refer to form 2 SOP-6001 for CA where the complaint resulted in a non-conformance)	
Mode of feedback to complainant (attach any supporting documents if applicable):	
Who provided feedback:	Date of feedback provided:
Is any further action needed?	Yes ☐ No ☐
Non-conformance opened?	Yes ☐ No ☐
FINAL APPROVAL	
I hereby acknowledge resolution of this complaint as satisfactory:	
Line Manager/Quality Coordinator/Director:	Date:

8. REFERENCES

- 8.1.1 ISO 15189
- 8.1.2 SOP-5025 Phlebotomy procedure
- 8.1.3 References for specific tests can be found in the SOP of the assay.