



(A Constituent Board of Quality Council of India)



CERTIFICATE OF ACCREDITATION

CHANRE DIAGNOSTIC LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

121/1, 3rd Main, Between 10th & 11th Cross, Margosa Road, Malleshwaram, Bangalore, Karnataka

in the field of

MEDICAL TESTING

Certificate Number

MC-3018 (in lieu of M-0260)

Issue Date

19/11/2018

Valid Until

18/11/2020

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Signed for and on behalf of NABL



Anil Relia

Chief Executive Officer





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SCOPE OF ACCREDITATION

Laboratory

ChanRe Diagnostic Laboratory, # 121/1, 3rd Main, Between 10th & 11th Cross, Margosa Road, Malleshwaram, Bangalore, Karnataka

Accreditation Standard

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SI.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limits of Detection	CV%
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CLINICAL BIOCHEMISTRY

1.	Serum	Albumin	Bromocresol Green	0.5 g/dl to 5.0 g/dl	2.2
2.	Serum	Albumin – Globulin ratio	Calculated	Limit of detection will vary as calculated method	NA
3.	Serum	Alkaline Phosphatase	Kinetic PNPP, AMP	18 U/L to 843 U/L	9.2
4.	Serum	Bilirubin Direct	Modified Jendrassik	0 mg/dl to 15 mg/dl	7.0
5.	Serum	Bilirubin Total	Modified Jendrassik	0 mg/dl to 20mg/dl	10.6
6.	Serum	Bilirubin Indirect	Calculated	Limit of detection will vary as calculated method	NA
7.	Serum	BUN	Calculated	Limit of detection will vary as calculated method	NA
8.	Serum	Creatinine	Jaffe Kinetic	0.29 mg/dl to 32.5 mg/dl	6.6
9.	Serum	Cholesterol Total	CHOD-PAP Enzymatic	33.4 mg/dl to 640 mg/dl	2.1
10.	Serum	C Reactive Protein	Nephelometry	1.0 mg/L to 80 mg/L	12.1
11.	Serum	C Reactive protein	Immunoturbidimetry	2 mg/L to 150 mg/L	6.1
12.	Serum	Calcium	Arsenazo III method	0.4 mg/dl to 23.69 mg/dl	2.1
13.	Serum	Chloride	Direct ISE method	50 mEq/L to 200 mEq/L	2.4
14.	Serum	Creatinine Phospho - Kinase (CPK)	Kinetic (DGKC)method	17 U/L to 2000 U/L	4.2
15.	Serum	Complement C3	Nephelometry	35 mg/dl to 350 mg/dl	10.4
16.	Serum	Ferritin	Electrochemiluminescence (ECLIA)	0.5 ng/ml to 2000 ng/ml	3.4
17.	Serum	Gamma Glutamyl transferase (GGT)	IFCC Method	7.6 U/L to 1285 U/L	4.2
18.	Serum	Globulin	Calculated	Limit of detection will vary as calculated method	NA
19.	Serum/Plasma	Glucose	GOD-PAP	6 mg/dl to 614 mg/dl	3.1

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20.	EDTA Whole Blood	HbA1c%	Immunoturbidimetry (Latex Agglutination Inhibition Assay)	0.25g/dl to 24g/dl	3.9
21.	EDTA Whole Blood	HbA1C%	HPLC	2% to 18%	6.0
22.	Serum	HDL-Cholesterol	Direct Estimation (Enzymatic Method)	1 mg /dl 150 mg /dl	4.6
23.	Serum	Iron	Ferrozine	11µg/dl to1098 µg/dl	6.6
24.	Serum	LDL-Cholesterol	Calculated	Limit of detection will vary as calculated method	NA
25.	Serum	Rheumatoid Factor (RF)	Latex-Enhanced Immunoturbidimetric Method	6.72 IU/mL to 104 IU/mL	7.6
26.	Serum	Rheumatoid Factor	Nephelometry	20 IU/ml to 800 IU/ml	10.1
27.	Serum	SGOT	IFCC without PLP	18.7 U/L to 657 U/L	4.0
28.	Serum	SGPT	IFCC without PLP	9.7 U/L to 666 U/L	4.0
29.	Serum	Total Cholesterol: HDL Cholesterol Ratio	Calculated	Limit of Detection will Vary as Calculated Method	NA
30.	Serum	Total Protein	Biuret	0.5 g/L to 12.4 g/L	3.4
31.	Serum	Triglyceride	GPO - Trinder's method	11.9 mg/dl to 1124 mg/dl	3.4
32.	Serum	Urea	Urease - GLDH Enzymatic UV Method	3 mg/dl to 300 mg/dl	6.0
33.	Serum	Uric acid	Enzymatic-colorimetric	0.35 mg/dl to 38.5 mg/dl	1.6
34.	Serum	VLDL-Cholesterol	Calculated	Limit of Detection will Vary as Calculated Method	NA
35.	Serum	Sodium	Direct ISE Method	40 mEq/L to 205 mEq/L	2.1
36.	Serum	Potassium	Direct ISE Method	1.5 mEq/L to 15 mEq/L	2.4
37.		Free Triiodothyronine (FT3)	Electrochemiluminescence (ECLIA)	0.26 pg/ml to 32.6 pg/ml	4.2
38.	Serum	Free Thyroxine (FT4)	Electrochemiluminescence (ECLIA)	0.02 ng/dl to 7.77 ng/dl	2.0

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39.	Serum	FSH(Follicle Stimulating Hormone)	Electrochemiluminescence (ECLIA)	0.1 mIU/mI to 200 mIU/mI	3.6
40.	Serum	LH (Luteinizing hormone)	Electrochemiluminescence (ECLIA)	0.1 mIU/mI to 200 mIU/mI	2.9
41.	Serum	Prolactin	Electrochemiluminescence (ECLIA)	0.47 ng/ml to 470 ng/ml	3.0
42.	Serum	β – HCG (Total)	Electrochemiluminescence (ECLIA)	0.1 mIU/mI to 10000 mIU/mI	4.5
43.	Serum	Immunoglobulin E (IgE)	Electrochemiluminescence (ECLIA)	0.100 IU/ml to 2500 IU/ml	3.9
44.	Serum	TSH (Thyroid stimulating hormone)	ECLIA/ MCLIA	0.005 mIU/mI to 100.0 mIU/mI	5.1/ 4.8
45.	Serum	T3 (Triiodothyronine)	ECLIA/ MCLIA	0.195 ng/ml to 6.51 ng/ml	7.7/
46.	Serum	T4 (Thyroxine)	ECLIA/ MCLIA	0.42 μg/dl to 24.86 μg/dl	5.2/ 7.9
47.	Serum	25-OH Vitamin D	ECLIA	3.4 ng/ml to155.9 ng/ml	13.7
48.	Serum	Vitamin B I2	ECLIA/ MCLIA	83 pg/ml to 2000 pg/ml	6.1/ 7.7

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CLINICAL PATHOLOGY

1.	Urine	Chemical_Analysis	Automated Method		
		Protein	Protein Error of Indicators Principle(Automated Strip Method)	Qualitative/ Semi Quantitative Detects Negative- 3.0 g/L	NA
		Glucose	Double Sequential Enzyme Reaction, Glucose Oxidase- Peroxidase Method(Automated Strip Reader)	Qualitative/ Semi Quantitative Detects Negative- 56µmol/L	NA
		рН	Double Indicator Principle (Automated Strip Reader)	Qualitative/ Semi Quantitative Detects 5.0-9.0	NA
		Specific Gravity	Apparent pKa Change in the Presence of Indicator Bromothymol Blue (Automated Strip Reader)	Qualitative/ Semi Quantitative Detects 1.005-1.030	NA
		Blood	Peroxidase-Method (Automated Strip Reader)	Qualitative/ Semi Quantitative Detects Negative to 200 Erythrocytes/µL	NA
		Bilirubin	Diazo Method (Automated Strip Reader)	Qualitative/ Semi Quantitative Detects Negative to 100.0 µmol/L	NA
		Leucocytes	Esterase Diazonium Reaction (Automated Strip Reader)	Qualitative/ Semi Quantitative Detects Negative to 500.0 Leucocytes/µL	NA
		Urobilinogen	Ehrlich Reaction (Automated Strip Reader)	Qualitative/ Semi Quantitative Detects 3.3-131.0µmol/L	NA

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		Ketone Bodies	Sodium Nitroprusside based method (Automated strip reader)	Qualitative: Semi Quantitative Detects Negative to 7.8 µmol/L	NA
		Nitrite	Diazo reaction-Conversion of Nitrate to Nitrite by the action of gram negative bacteria in urine (Automated strip reader)	Qualitative/Semi quantitative detects Negative/Positive in µmol/L	NA
2.	Urine	Chemical Analysis	Manual (Dipstick)		
		Protein	Protein Error of Indicators Principle (Visual Reading)	Qualitative/ Semi Quantitative Detects Negative to 20.0 g/L	s ol/L
		Glucose	Double Sequential Enzyme Reaction- Glucose Oxidase- Peroxidase Method (Visual Reading)	Qualitative/ Semi Quantitative Detects Negative to 56 µmol/L	NA
		рН	Double Indicator Principle (Visual Reading)	Qualitative/ Semi Quantitative Detects 5.0-8.5	NA
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		Specific Gravity	Apparent pKa Change in the Presence of Indicator Bromothymol Blue (Visual Reading)	Qualitative/ Semi Quantitative Detects 1.000-1.030	NA
		Blood	Peroxidase-Method (Visual Reading)	Qualitative/ Semi Quantitative Detects Negative to 200 Erythrocytes/µL	NA
		Bilirubin	Diazo Method (Visual Reading)	Qualitative/ Semi Quantitative Detects Negative to 100.0 µmol/L	NA
		Leucocytes	Esterase Diazonium Reaction (Visual Reading)	Qualitative/ Semi Quantitative	NA

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				Detects Negative to 500.0 Leucocytes/µL	
		Urobilinogen	Ehrlich Reaction (Visual Reading)	Qualitative/Semi Quantitative Detects 3.3-131.0 µmol/L	NA
		Ketone bodies	Sodium Nitroprusside Based Method (Visual Reading)	Qualitative/Semi Quantitative Detects Negative to 16 µmol/L	NA .
		Nitrite	Diazo Reaction- Conversion of Nitrate to Nitrite by the Action of Gram Negative Bacteria in Urine (Visual Reading)	Qualitative: Detects Negative/Positive in 16 µmol/L L	NA
	Urine Sediment	Microscopy	Light Microscopy for Cells, Casts, Crystals, Microorganisms	Descriptive, Hence Not Applicable	NA

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HAEMATOLOGY & IMMUNOHAEMATOLOGY

1.	EDTA Blood	Hemoglobin	Particle Cell Counter (SLS Haemoglobin Detection Method)	0.1 g/dl to 25.0 g/dl	1.4
2.	EDTA Blood	Total WBC Count	Particle Cell Counter -5 Part, Optical Detector Block Based on Flow Cytometry Method Using a Semiconductor Laser	0 /μL to 400000/μL	2.2
3.	EDTA Blood	RBC Count	Particle Cell Counter -5 Part, Hydrodynamic Focusing Method	0/ µL to 8000000/ µL	2.4
4.	EDTA Blood	HCT (Hematocrit Value)	Particle Cell Counter -5 Part	1.0% to 60.0 %	2.8
5.	EDTA Blood	MCV (Mean Corpuscular Volume)	Particle Cell Counter -5 Part.	Calculated from RBC histogram hence range is not applicable. Unit: fL	NA
6.	EDTA Blood	MCH (Mean Corpuscular Hemoglobin)	Calculated from Haemoglobin valve by SLS Hb Detection Method and RBC by Hydrodynamic Focusing Method	Calculated parameter, hence range is not applicable Unit: pg	NA
7.	EDTA Blood	MCHC (Mean corpuscular Hemoglobin Concentration)	Particle Cell Counter -5 Part	Calculated according to Hemoglobin and PCV values hence range is not applicable. Unit: g/dl	NA
8.	EDTA Blood	Platelet Count	Particle Cell Counter -5 Part, Electrical Impedence Principle	0/ μL to 2000000/ μL	7.4

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9.	EDTA Blood	Neutrophils %	Automated Cell Counter -5 Part (Flow Cytometry Method)	0 - 100%	6.6
10.	EDTA Blood	Lymphocytes %	Automated Cell Counter – 5 Part (Flow Cytometry Method)	0 - 100%	13.9
11.	EDTA Blood	Monocytes %	Automated Cell Counter – 5 Part (Flow Cytometry Method)	0 - 100%	98.6
12.	EDTA Blood	Eosinophils %	Automated Cell Counter – 5 Part (Flow Cytometry Method)	0 - 100%	7.4
13.	EDTA Blood	Basophils %	Automated Cell Counter – 5 Part (Flow Cytometry Method)	0 - 100%	10.2
14.	EDTA Blood	Absolute Neutrophil Count	Automated Cell Counter – 5 Part (Flow Cytometry Method)	Calculated parameter Unit: X10 ³ uL	NA
15.	EDTA Blood	Absolute Lymphocyte Count	Automated Cell Counter – 5 Part (Flow Cytometry Method)	Calculated parameter Unit: X10 ³ uL	NA
16.	EDTA Blood	Absolute Monocyte Count	Automated Cell Counter – 5 part (Flow Cytometry method)	Calculated parameter Unit: X10 ³ uL	17.7
17.	EDTA Blood	Absolute Eosinophil Count	Automated Cell Counter – 5 part (Flow Cytometry method)	Calculated parameter Unit: X10 ³ uL	6.8
18.	EDTA Blood	Absolute Basophil Count	Automated Cell Counter – 5 Part (Flow Cytometry Method)	Calculated parameter Unit: X10 ³ uL	NA
19.	EDTA Blood	RDW SD	Particle Cell Counter -5 Part, Electrical impedence Method	Calculated parameter Unit: Fl	NA
20.	EDTA Blood	RDW CV	Particle Cell Counter -5 Part, Electrical impedence Method	Calculated parameter Unit: %	0.8

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21.	EDTA Blood	MPV (Mean Platelet volume)	Particle Cell Counter -5 Part	Calculated parameter hence range is not applicable. Unit: fL	1.7
22.	EDTA Blood	PCT (Plateletcrit)	Particle Cell Counter -5 Part	Calculated parameter hence range is not applicable. Unit: %	5.3
23.	Citrated Plasma	PT (Prothrombin Time)	Fully Automated Coagulation Analyzer (CA-500). Photo Optical Clot Detection Method	0 Sec to 120 Sec	8.3
24.	Citrated Plasma	PT (Prothrombin Time)	Semi-Automated Coagulation Analyzer (Mechanical Clot Detection System) End Point Method	0 Sec to 120 Sec	1.8
25.	Citrated Plasma	PT INR	Fully Automated Coagulation Analyzer (CA- 500). Photo Optical Clot Detection Method	Qualitative : Calculated based on PT and ISI value of reagent	NA
26.	Citrated Plasma	PT INR	Calculated	Others: Calculation based on PT and ISI value of reagent	NA
27.	Citrated - Plasma	APTT (Activated Partial Thromboplastin Time)	Fully Automated Coagulation Analyzer, Photo Optical Clot Detection Method.	0 Sec to 190 Sec	10.5
28.	Plasma	APTT (Activated Partial Thromboplastin Time)	Semi-Automated Coagulation Analyzer (Mechanical Clot Detection System) Phospholipid Reagent with Particulate Activator	0 Sec to 120 Sec	0.9
29.		Peripheral smear Examination	Manual Staining and Microscopy	Others: NA	NA

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30.	EDTA Blood	Reticulocyte Count	Supravital Staining and Smear study	Others: Stain used for the test is Brilliant Cresyl Blue	NA
31.	EDTA Blood	Erythrocyte Sedimentation Rate (ESR)	Westergren method Automated ESR analyzer	0mm/hr to 200 mm/hr	9.6
32.	Citrated Plasma	LA (Lupus Anticoagulant)	Photo optical clot detection method-DRVVT (Dilute Russel Viper Venom Test)	Qualitative Calculated parameter hence range is not applicable. Unit: Seconds	NA

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MICROBIOLOGY & SEROLOGY

1.	Serum	Anti-Nuclear Antibody (ANA)	Immuno Fluorescence Method	Qualitative/NA	NA
2.	Serum	Anti-Neutrophil Cytoplasmic Antibody (ANCA)	Immuno Fluorescence Method	Qualitative/NA	NA
3.	Serum	Anti-nuclear antibody (ANA) profile -Sm/RNP -Sm -SS-A native - Ro-52 - SS- Scl-70 - PM-Scl - Jo-1 - Centromere B - PCNA - dsDNA - Nucleosome - Histones - Ribosomal-P- Protein -AMA-M2	Immuno Blot Method	Qualitative /NA	NA
4.	Serum	ANA Profile (Antinuclear antibody profile) - Nucleosome - dsDNA - Histones - Sm - RNP - Sm/RNP - SSA/Ro60 kD	Microdot-Immunoassay (Quantrix)	Qualitative /NA	NA

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		- SSA/Ro52 kD - SSB - ScI-70 - Ku - PM-ScI 100 - Mi-2 - Jo-1 - PL-7 - PL-12 - SRP-54 - Ribosome P0 - CENP-A/B - PCNA - sp100 - gp210 - M2 recombinant - M2/nPDC - f-Actin			
5.	Serum	ANCA Profile - MPO antibody - PR3 antibody - GBM antibody	Immuno blot method	Qualitative /NA	NA
6.	Serum	Chikungunya IgM	Lateral Flow Chromatographic Immunoassay	Qualitative /NA	NA
7.	Serum	Dengue NS1 Ag & IgG& IgM Ab		Qualitative /NA	NA
8.		Anti-CCP		0.3 RU/ml to 200 RU/ml	11.9
9.		ACLA IgG	ELISA method	0.8 PL- IgG-U/ml to 120 PL- IgG-U/ml	15.0
10.	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	ACLA IgM	ELISA method	1.6 PL-IgM-U/mI to 120 PL-IgM-U/mI	14.6
11.		ß2-Glycoprotein IgG			10.0

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12.	Serum	ß2-Glycoprotein IgM	ELISA method	0.8 RU/mI to 200 RU/mI	8.8
13.	Heparinized Blood	Quantiferon TB Gold	ELISA method	Qualitative: NA	NA
14.	Serum	Myositis profile -Mi-2 -Ku -PM-Scl 100 -PM-Scl 75 -Jo-1 -SRP (Signal Recognition Particle) - PL-7 - PL-12 - EJ (Glycyl t- RNA synthetase)	Immuno blot method	Qualitative: NA	NA
		- OJ (Isoleucyl t- RNA synthetase) - Ro-52			
15.		Allergy: Food - Cow's Milk - Egg yolk - Milk Powder - Wheat flour - Rice - Soybean - Peanut - Coconut - Apple - Grape - Potato - Spinach - Onion - Cucumber - Chicken	Immunoblot	Qualitative/NA	N/A

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SI.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limits of Detection	CV%
		- Mustard - Coffee - Ginger - Crab - Shrimp - Prawn Allergy: Inhalants - Timothy grass - Cultivated rye - Cultivated corn - Eucalyptus - False ragweed - Carnation flower - Sunflower - House dust mite mix1 - Dermatophagoid es farina - Cockroach, German - Cat epithelium - Dog epithelium - Digeon feathers - Chicken feathers - Aspergillus fumigatus - Cotton - Straw dust - Jute Sheep			

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1	1			1		1

HISTOPATHOLOGY

1.	Formalin Fixed Tissue	Gross Examination, Routine Processing And Microtomy, H&E Staining (Decalcification, if Necessary).	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
2.	Formalin Fixed Paraffin Embedded Tissue Sections for Opinion	Routine H & E Staining	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
3.	Formalin Fixed Paraffin Embedded Tissue (Block) For Opinion	Microtomy H&E Staining (Conventional)	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
4.	Formalin Fixed Paraffin Embedded Tissue Block / Unstained Slide	PAS stain McManus method	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
5.	Formalin Fixed Paraffin Embedded Tissue Block / Unstained Slide	Modified Fite Faracco Stain	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
6.	Formalin Fixed Paraffin Embedded	Ziehl Neelsen stain	Light microscopy and interpretation	Descriptive, Hence Not Applicable	NA

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SI.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limits of Detection	CV%
	Tissue Block / Unstained Slide				
7.	Formalin Fixed Paraffin Embedded Tissue Block / Unstained Slide	Alcian Blue Stain	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA

K. Udaya Bhaskhar Convenor





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(A Constituent Board of Quality Council of India)

SCOPE OF ACCREDITATION

Laboratory

ChanRe Diagnostic Laboratory, # 121/1, 3rd Main, Between 10th & 11th Cross, Margosa Road, Malleshwaram, Bangalore, Karnataka

Accreditation Standard

ISO 15189: 2012

Certificate Number

MC-3018 (in lieu of M-0260)

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Validity

19.11.2018 to 18.11.2020

Last Amended on --

SI.	Product / Material of Test	Specific Test Performed	Test Method	Range of Testing / Limits of Detection	CV%
	<u> </u>		<u> </u>		

CYTOPATHOLOGY

1.	Palpable or Non-Palpable Lesion Involving Any Organ	FNA, Smear/Cell Block Preparation and Stain- MGG with /without PAP/H&E	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
2.	Body Fluids (Ascitic, Pleural, Synovial, BAL Pus, Nipple Discharge Etc.)	Centrifugation, Smear/Cell Block Preparation and Stain- H&E/ PAP, MGG s	Light Microscopy with Interpretation	Descriptive, Hence Not Applicable	NA
3.	Unstained Cytology Smears	MGG with/without PAP/H&E Stains	Light Microscopy with Interpretation	Descriptive, Hence Not Applicable	NA
4.	Scrapings/ Brushings (GIT, Bronchial, Oral)	MGG with/without PAP/H&E Stains	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
5.	Cervical; Vaginal Smears (Conventional)	PAP Stain	Light Microscopy and Interpretation	Descriptive, Hence Not Applicable	NA
6.	Cervical; Vaginal Smears-Liquid Based Cytology (LBC)	PAP Stain	Light Microscopy and Interpretation	Qualitative: NA	NA

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