

# Quality And Accreditation Institute Centre for International Accreditation

(formerly Centre for Laboratory Accreditation)



## Certificate of Accreditation

***Sigma Diagnostics Laboratory Pvt. Ltd.***

*Radhe Radhe, Madhyapur Thimi-09,  
Bhaktapur, Nepal*

*has been assessed and accredited in accordance with the Standard*

***ISO 15189:2022***

*“Medical Laboratories - Requirements for Quality and Competence”*

*In the field of*

***Medical Testing***

*This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued compliance to the above standard & any other requirements specified by QAI.*



***QAI/CIA/ML/2024/0027***

*Valid from: 10 December 2024*

*Valid until: 09 December 2026*

***Dr. Bhupendra Kumar Rana***  
*Chief Executive Officer*

***Prof. Vikram Kumar***  
*Chair, CIA*

*User is advised to verify the current scope of accreditation by visiting our website: [www.qai.org.in](http://www.qai.org.in)*



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### Scope of Accreditation

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*Accreditation Standard: ISO 15189:2022*

Clinical Biochemistry and Immunoassay						
Sl. No.	Type of Sample Examined/ Tested	Specific Tests/ Performed	Examination	Standard	(Method),	Principle/ Methodology or Technique Used
1.	Serum/ fluoride plasma	Sugar		Hexokinase		
2.	Serum	Urea		Urease Kinetic		
3.	Serum	Creatinine		Creatinine PAP		
4.	Serum	Uric acid		Uricase Peroxidase		
5.	Serum	Cholesterol		Cholesterol Oxidase		
6.	Serum	Triglycerides		Glycerol phosphate oxidase (GPO)		
7.	Serum	Serum glutamic-pyruvic transaminase (SGPT)/ Alanine aminotransferase (ALT)		International Federation of Clinical Chemistry (IFCC)		
8.	Serum	Serum Glutamic-Oxaloacetic Transaminase test (SGOT)/ Aspartate aminotransferase (AST)		International Federation of Clinical Chemistry (IFCC)		
9.	Serum	Alkaline Phosphatase (ALP)		AMP IFCC		
10.	Serum	Total Bilirubin		Oxidation to Biliverdin		
11.	Serum	Direct Bilirubin		Oxidation to Biliverdin		
12.	Serum	Total Protein		Biuret reaction end point		
13.	Serum	Albumin		Bromocresol green		
14.	Serum	Gamma -glutamyl transferase (GGT)		International Federation of Clinical Chemistry (IFCC)		
15.	Serum	Calcium		Arsenazo III assay		
16.	Serum	Iron		Colorimetric without ppt		
17.	Serum	Amylase		Roche liquid stable		
18.	Serum	Lipase		Roche colometric		
19.	Serum	Sodium		Ion selective electrode (ISE)		
20.	Serum	Potassium		Ion selective electrode (ISE)		

*This is annexure to 'Certificate of Accreditation' and does not require any signature.*

[www.qai.org.in](http://www.qai.org.in)



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Clinical Biochemistry and Immunoassay						
Sl. No.	Type of Sample Examined/ Tested	Specific Tests/ Examination Performed	Standard (Method), Principle/ Methodology or Technique Used			
21.	Serum	Lactate dehydrogenase (LDH)	International Federation of Clinical Chemistry (IFCC)			
22.	Serum	Magnesium	Xylidyl Blue			
23.	Serum	Phosphorus	Phosphomolybdate UV			
24.	Serum	Alpha-fetoprotein (AFP)	eCLIA			
25.	Serum	Cancer antigen 125	eCLIA			
26.	Serum	Carcinoembryonic antigen (CEA)	eCLIA			
27.	Serum	Cortisol	eCLIA			
28.	Serum	C-Peptide	eCLIA			
29.	Serum	Ferritin	eCLIA			
30.	Serum	Follicle-stimulating hormone (FSH)	eCLIA			
31.	Serum	Beta-human chorionic gonadotropin (B-HCG)	eCLIA			
32.	Serum	Insulin	eCLIA			
33.	Serum	Luteinizing hormone (LH)	eCLIA			
34.	Serum	Prolactin	eCLIA			
35.	Serum	Prostate-specific antigen (PSA), total	eCLIA			
36.	Serum	Free T3	eCLIA			
37.	Serum	Free T4	eCLIA			
38.	Serum	Thyroid-stimulating hormone (TSH)	eCLIA			
39.	Serum	Thyroglobulin	eCLIA			
40.	Serum	Vitamin B12	eCLIA			
41.	Serum	Vitamin D (25-OH)	eCLIA			

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Clinical Biochemistry and Immunoassay			
Sl. No.	Type of Sample Examined/ Tested	Specific Tests/ Performed	Standard (Method), Principle/ Methodology or Technique Used
42.	Serum	Testosterone	eCLIA



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Haematology			
Sl. No.	Type of Sample Examined/ Tested	Specific Tests/ Examination Performed	Standard (Method), Principle/ Methodology or Technique Used
1.	Whole Blood	Haemoglobin	Coulter Counter
2.	Whole Blood	Red blood cell (Impedance Count)	Coulter Counter
3.	Whole Blood	White blood cell (Impedance Count)	Coulter Counter
4.	Whole Blood	Platelet (Impedance Count)	Coulter Counter
5.	Whole Blood	Haematocrit (HCT) and packed cell volume (PCV)	Coulter Counter
6.	Whole Blood	Mean cell volume (M.C.V.)	Coulter Counter
7.	Whole Blood	Mean cell haemoglobin (M.C.H.)	Coulter Counter
8.	Whole Blood	Mean cell haemoglobin concentration (M.C.H.C.)	Coulter Counter
9.	Whole Blood	Mean platelet volume (MPV)	Coulter Counter
10.	Whole Blood	Red cell distribution width CV	Coulter Counter

