

Health problem and current use of technology domain [12,18-22]			
Target population	Target condition	Current management of the condition	
Affected by DM (5.9% of the Italian population) and at risk; individuals with suspected hemoglobinopathy (carried by 10% of the Italian population) and those undergoing neonatal screening	<ul style="list-style-type: none"> <li>DM and its complications: HbA1c is utilized for both diagnosis and therapy</li> <li>Hemoglobinopathies: Hemoglobin variants are employed in screening, diagnosis, and therapy</li> </ul>	HbA1c is a useful measure of treatment efficacy, providing an integrated summary of circadian blood glucose over the preceding 6-8 weeks.	
Technical characteristics domain [14,15,16,23]			
	Sebia Capillars 2 Flex-piercing	Tosoh HLC-723 G11	
Type of Instrument	Automated analyzer based on capillary electrophoresis	HPLC with ion exchange	
Quantitative Analysis	Hemoglobin fractions A, A2, and F; Detection of major variants S, C, E, and D	Separation of HbA1a, HbA1b, HbF, Labile HbA1c, Stable HbA1c, HbA0	
Detection Method	Absorbance at 415 nm; Specific detection of hemoglobins	Absorbance at 415 nm/500 nm; High-resolution chromatograms	
Results Expression	IFCC and NGSP units	Elution time differences for HbA1c values	
Separation Considerations	Challenges of glycated HbA1c co-elution; Results expressed in both units	HbA1c eluted ahead of HbA, leading to potential overestimation/underestimation of HbA1c values	
Safety domain [13,18,24]			
Risk for patients	Hemoglobin Qualitative Abnormalities	Instrument Parameters	Safety of Healthcare Workers
The incorrect diagnosis and inaccurate quantification of HbA1c can adversely affect treatment decisions	The risk of unexpectedly identifying a hemoglobin variant and obtaining a false negative result may impact the assessment of hemoglobin structure	<ol style="list-style-type: none"> <li>Certified by the NGSP precision, linearity, and reliability parameters for HbA1c measurement and diabetes control</li> </ol>	Disposal of biological materials and toxic waste.
Clinical effectiveness [23,25-35]			
	Sebia Capillars 2 Flex-piercing	Tosoh HLC-723 G11	
Accuracy	CV < 2.5%, good linearity	CV < 2%, good linearity	
	Both analyzers have been certified by the NGSP		
Correlation Between Analyzers	<ul style="list-style-type: none"> <li>Good correlation for HbA1c (<math>R^2=0.972</math>), decreases near diagnostic threshold (<math>R^2=0.7032</math>).</li> <li>Reasonable correlation for HbF (<math>R^2=0.9274</math>) and HbS (<math>R^2=0.9667</math>)</li> <li>Lower correlation for HbA2 (<math>R^2=0.658</math>)</li> <li>HPLC and CE identified as complementary methods for accurate hemoglobin variant quantification</li> </ul>		
Organisational aspects domain [28,36]			
	Sebia Capillars 2 Flex-piercing.	Tosoh HLC-723 G11	
Analyzers Characteristics	Perform analysis on whole or diluted blood (EDTA) Record analytical sessions Connect to the Laboratory Information System (LIS) Usage by trained Laboratory Medicine personnel in a biomedical laboratory		
Turnaround Time	Provides 38 results per hour	HLC-723 G11 Variant Mode: 3' for one sample, 12' for 10 samples, 31' for 30 samples. HLC-723 G11 Standard Mode: 1' for one sample, 7' for 10 samples, 18' for 30 samples	
Analyzer Differences	at risk of obsolescence about a 70% difference in quotation between the two instruments a newly released instrument		
Impact on the patient and society domain [31, 37-39]			
Patients perception	Clinical Impact	Diabetes Management	Hemoglobinopathies Control
No direct perception of the laboratory test technology by the patients	<ol style="list-style-type: none"> <li>Contribution to overall patient outcomes</li> <li>comprehensive view of a patient's Hb profile for clinicians</li> </ol>	It is crucial in public health management	critical in high-risk geographical areas
Ethical domain [39]			
Ethical aspects	Benefit-harm balance		
No differences	A detailed Hb profile assessment may uncover new variants, occasionally leading to critical hematological phenotypes when combined with beta and alpha chain defects.		
Legal domain [40]			
Essential levels of assistance (LEA)	Italian National Health Service (SSN)		
Laboratory tests for DM and haemoglobinopathies are included in the LEA.	SSN is required to provide to all citizens ((DPCM, 2017)		
Color code:	No difference between analyzers		Difference between analyzers