

Essential Data Elements for Laboratory Test Interoperability: An Expert Consensus-Based Framework

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Supplemental Data Table S1. List of all committee members in the Guideline Development Group

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Supplemental Data Table S2. Comparison of Relevant Standards and Guidelines Referenced for Laboratory Data Elements

Data categories	Data elements	Tier 1 (Data for CDI)	Tier 2 (Data for Report)	Tier 3 (Data for Laboratory)	Relevant standards and guidelines						
					Required for laboratory report				Required for semantic interoperability		
					ISO 15189:2022	CLIA § 493.1291	CAP GEN.41096	LMF OLAP	CLSI AUTO17-ED1:2023	USCDI V6	KR CDI V2
Patient data	Patient name	Y	Y	Y	Y	Y	Y	Y		Y (Patient Demographics/Information)	Y
	Identification number	Y	Y	Y	Y	Y	Y	Y			Y
	Sex	Y	Y	Y				Y		Y (Patient Demographics/Information)	Y
	Date of birth	Y	Y	Y				Y		Y (Patient Demographics/Information)	Y
Test data	Test information										
	Name of test	Y	Y	Y	Y	Y	Y	Y	Y	Y (Laboratory)	Y
	Test methods		Y (when applicable)	Y	Y (where relevant)	Mentioned (upon request)					
	UDI for instruments and reagents			Y					Y	Y (Laboratory, Level 1, instrument only)	
	Result information										
	Test result	Y	Y	Y	Y	Y	Y	Y	Y	Y (Laboratory)	Y
	Unit of measurement	Y (when applicable)	Y (when applicable)	Y (when applicable)	Y (where appropriate)	Y (if applicable)	Y (when applicable)	Y	Y	Y (Laboratory)	
	Reference intervals	Y (when applicable)	Y (when applicable)	Y (when applicable)	Y (as necessary)	Mentioned (available only)	Y (as applicable)	Y (if applicable)		Y (Laboratory)	Y
	Clinical decision limits	Y (when applicable)	Y (when applicable)	Y (when applicable)	Y (as necessary)			Y (if applicable)			
	Result	Y (when applicable)	Y (when applicable)	Y (when applicable)	Y (when applicable)	Y (if applicable)		Y (if applicable)	Y	Y (Laboratory)	Y
	Interpretation	Y (when applicable)	Y (when applicable)	Y (when applicable)				Y (if applicable)			
	Result status	Y (when applicable)	Y (when applicable)	Y	Y					Y (Laboratory)	Y
	Notification information										
	Critical value flag			Y (when applicable)	Mentioned (procedure only)	Mentioned (procedure only)					
	Error flag			Y (when applicable)		Mentioned (procedure only)					
	Delayed report notification			Y (when applicable)	Mentioned (procedure only)	Mentioned (procedure only)					
Specimen data	Specimen identifier			Y	Y					Y (Laboratory)	

Data categories	Data elements	Tier 1 (Data for CDI)	Tier 2 (Data for Report)	Tier 3 (Data for Laboratory)	Relevant standards and guidelines					
					Required for laboratory report			Required for semantic interoperability		
					ISO 15189:2022	CLIA § 493.1291	CAP GEN.41096	LMF OLAP	CLSI AUTO17-ED1:2023	USCDI V6 KR CDI V2
	Specimen type	Y	Y	Y	Y			Y (when applicable)	Y	Y (Laboratory)
	Specimen site	Y (when applicable)	Y (when applicable)	Y (when applicable)	Y (when necessary)	Y (when appropriate)	Y (when applicable)	Y (when applicable)	Y	Y (Laboratory)
	Specimen quality	Y	Y	Y	Y (when applicable)	Y	Y	Y (if applicable)		Y (Laboratory)
Date/Time data	Specimen collection date	Y	Y	Y	Y		Y	Y (if applicable)		Y (Laboratory, Level 0)
	Specimen collection time	Y (when applicable) Y (when feasible)	Y (when applicable) Y (when feasible)	Y (when applicable) Y (when feasible)	Y (when necessary for patient care)		Y (if appropriate)	Y (if applicable)		Y (Laboratory, Level 0)
	Specimen received date/time	Y	Y	Y	Mentioned (record only, when relevant)			Y		Y (Laboratory, Level 0)
	Test performed date/time			Y				Y		Y (Laboratory, Level 0)
	Test reported date/time	Y	Y	Y	Y	Y (time: not indicated)	Y (time: if applicable)	Y		Y (Laboratory, Level 0)
	Y									Y
Administration data	Laboratory information									
	Laboratory name	Y	Y	Y	Y	Y	Y	Y		Y (Facility Information)
	Laboratory address	Y	Y	Y	Mentioned (not for report)	Y	Y	Y (in referral laboratory)		Y
	Laboratory contact	Y	Y	Y	Mentioned (not for report)			Y		Y
	Laboratory quality									
	Accreditation status		Y	Y	Mentioned (not for report)			Y (when applicable)		
	External quality assessment status		Y	Y	Mentioned (not for report)					
	Personnel information									
	Requesting physician	Y	Y	Y	Y	Mentioned (procedure only)	Y	Y		Y (Care Team Members)
	Performing personnel		Y	Y	Mentioned (record only)			Y		Y (Provenance)
	Reporting personnel		Y	Y	Y (if not in report, readily available)			Y		Y (Provenance)
	Specialist review and approval		Y	Y	Y (when applicable)			Y (when required)		