

Core data elements version 3 (Feb 25, 2021): Serological Assay Results

CITF Domain	Number		Label	Type	Technical specs	Comment
SEROLOGY	101		Project ID	Free text	Unconstrained alphanumeric string	Harmonize with Project funding ID and across platforms. See User Guide Appendix I – List of CITF Projects IDs.
SEROLOGY	102		Laboratory/Facility name	Free text	Unconstrained alphanumeric string	
SEROLOGY	103		Laboratory/Facility zip code	Free text	Unconstrained alphanumeric string	
SEROLOGY	104		Specimen source	Categorical	SCT code: Serum (119364003) / Plasma (119361006)/ Dried blood spot (440500007)	
SEROLOGY	105		Participant ID	Free text	Unconstrained alphanumeric string	Must be unique value. CITF data manager will provide guidance that follows HL7 standards. May be left blank.
SEROLOGY	106		Specimen ID	Free text	Unconstrained alphanumeric string	Must be unique value, and follow HL7 specs for documentation. Example: Barcode on specimen.
SEROLOGY	107		Specimen collection date	Date	YYYY[MM[DD]]	May be left blank if not available
SEROLOGY	108		Overall description	Categorical	SCT code: Positive (10828004) / Negative (260385009) / Inconclusive (419984006)	Result from orthogonal testing algorithm Example: positive if at least 2 of the 3 assays are positive.
SEROLOGY	109		Comments	Free text	Unconstrained alphanumeric string	Space for additional notes not covered in the other lines. Example: test batch ID for StatCan samples or Error codes.
SEROLOGY	110	Multiple assays block*	CITF Assay ID	Categorical	Unconstrained alphanumeric string	Unique number. See User Guide – 3. CITF Assay List (Includes fixed information: assay type, Ab, Ag, units, lots, etc)
SEROLOGY	111		Date assay run	Date	YYYY[MM[DD]]	
SEROLOGY	112		Antigen tested	Categorical	Unconstrained alphanumeric string	Unique name. See User Guide – 3. CITF Assay List
SEROLOGY	113		Result	Numerical	Unconstrained numeric string	See User Guide – 3. CITF Assay List.
SEROLOGY	114		Cutoff	Numerical	Unconstrained numeric string	Value above which the samples is considered positive
SEROLOGY	115		Maximum	Numerical	Unconstrained numeric string	Highest measurable number for semiquantitative data or higher value of standard curve for quantitative data
SEROLOGY	116		Results description	Categorical	SCT code: Positive (10828004) / Negative (260385009) / Inconclusive (419984006)	See other available option in User Guide section 2 Table 1.
SEROLOGY	117		Pass QC?	Categorical	SCT code: Yes (373066001) / No (373067005)	If No, possible to add more in Comments, see available options in User Guide section 2 Table 1.

* Assay block of items should be repeated for each assay (and antigen, in the case of multiplex assays).

Codes and additional instructions are listed in the “CORE DATA ELEMENTS for Reporting of Serological Assay Results: User Guide”