



QUALITY ASSURANCE TESTING, EQUIPMENT AND SERVICES

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Gage Crib Worldwide, Inc.

<https://www.gagecrib.com/>

**Guidance to the required reference connectors and equipment for testing connectors for reservoir delivery systems for healthcare applications - Citrate-based anticoagulant solution for apheresis applications**

ISO 18250-8:2018 Reference Connectors and ISO 80369-20:2015 Test Equipment			
ISO 18250-8 Clause	ISO 80369-20 Annex	Enersol equipment required	Required Enersol reference connectors for testing AC Reservoir connectors
Clause 5 - all sub-clauses	The test methods require the test sample is assembled with the appropriate reference connector, using a specified force and/or torque to assemble them.	S15B - Connector assembly device	Any/all reference connectors listed below
Clause 5.2 - Positive pressure liquid leakage	Annex C - Positive Pressure Liquid Leakage	S16B - Positive pressure liquid leakage tester	S72 - Fig. C.1 - CC for testing SC S73 - Fig. C.2 - SC for testing CC
Clause 5.3 - Stress cracking	Annex E - Stress cracking	Use S15B and S16B	S72 - Fig. C.1 - CC for testing SC S73 - Fig. C.2 - SC for testing CC
Clause 5.4 - Resistance to separation from axial load	Annex F - Resistance to separation from axial load	S18B - Separation force device	S74 - Fig. C.5 - CC for testing SC S75 - Fig. C.6 - SC for testing CC
Clause 5.5 - Resistance to separation from unscrewing	Annex G - Resistance to separation from unscrewing	S19A - Unscrewing torque device	S72 - Fig. C.1 - CC for testing SC S73 - Fig. C.2 - SC for testing CC
Clause 5.6 - Resistance to overriding	Annex H - Resistance to overriding	Use S15B	S74 - Fig. C.5 - CC for testing SC S75 - Fig. C.6 - SC for testing CC
Clause 5.7 - Subatmospheric pressure air leakage***	Annex D - Subatmospheric pressure air leakage***	S78B - Automated subatmospheric pressure air leakage tester*** Or for locations 900m or more above sea level, the S78H is required for this test	S72 - Fig. C.1 - CC for testing SC S73 - Fig. C.2 - SC for testing CC

KEY: SC = Socket (Female) Connector CC = Cone (Male) Connector

\*\*\* = NOTE: For laboratories located at 600m-899m or at 900m or more above sea level, please let Enersol know as this affects the S78B units where 80-88kPa subatmospheric pressure is required.