

Refractrol™ SP Serum Protein Reference Controls For use on Refractometers

INTENDED USE

Refractrol™ SP is a reference control consisting of bovine serum albumin in a synthetic matrix. It is intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures for total serum protein values, as measured by digital and analog refractometer procedures. Refractrol SP controls are provided with quantitative concentration values obtained by testing on multiple refractometry systems. For professional laboratory use only.

SUMMARY AND PRINCIPLE

Good Laboratory Practice (GLP) procedures require that stable reference materials be used to verify the performance of testing methods and techniques. Refractrol SP may be used as one would use human serum to obtain the stated total protein values.

MATERIALS PROVIDED

Refractrol SP is an in vitro diagnostic control composed of buffered bacteriostatic and fungistatic fluid in a formulation that mimics serum.

Product Number	Description - Refractrol	Pack Size
84652	Refractrol™ SP Low	12 x 2mL
84653	Refractrol™ SP Normal	12 x 2mL
84654	Refractrol™ SP High	12 x 2mL

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use

CAUTION: Handle Refractrol controls and all products containing animal-derived components as though capable of transmitting infectious agents.

Refractrol SP is made entirely from non-human components. However, because no test method can offer complete assurance that infectious agents are absent, it is recommended that these products be handled with the same precautions used for patient specimens. Use the Centers for Disease Control (CDC) recommended universal precautions¹ for handling Refractrol controls and patient specimens. Do not pipette by mouth; do not eat or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens, controls and materials used in testing as though they contain infectious agents. Additional safety information can be found in the product Safety Data Sheet (SDS) found on the company website. Refractrol SP is not intended for use as a Certified Reference Material that is traceable to a metrological standard. Quantitative values from refractometry systems are reported for quality assurance purposes only.

STORAGE AND STABILITY

Refractrol SP is stable in the unopened vial until the expiration date stated on the label when stored between 15° - 30°C. Refractrol SP has an open vial stability of up to 14 days.

PROCEDURE

Follow the manufacturer's instructions provided with the Digital or Analog refractometer for serum protein procedures.

1. Verify that the lot number on the vial matches the assay sheet.
2. Gently invert the vial to mix, making sure air bubbles are not introduced to the control.
3. To avoid evaporation, do not leave the vial uncapped.
4. Make sure all vials are at room temperature before testing.
5. If the liquid in the vial becomes frozen, allow the vial to reach room temperature and mix the vial thoroughly by inverting each vial several times before testing.

Controls should be run on the refractometer:

- daily, in conjunction with patient samples.
- as recommended by the instrument manufacturer.
- as required by the relevant regulatory agency.

EXPECTED VALUES

An expected range for each level is provided on the batch specific Assay Sheet, available at www.seracare.com/resourcelibrary. A lab shall use the provided range as the acceptable target values and ranges for quality control as long as the lab follows the manufacturer's instructions provided with the Digital and Analog Refractometer.

LIMITATIONS OF THE PROCEDURE

1. Serum protein assay values listed on the provided Assay sheet are valid for refractometry methods only. They may not be valid for test methods other than refractometry.
2. Refractrol controls must not be substituted for the positive and negative control reagents provided with manufactured test kits.
3. TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed.
4. Refractrol controls are provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure.
5. Variations in instruments and temperature of the testing material may result in accuracy and linearity variations.
6. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

BIBLIOGRAPHY

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400.

Any serious incident that has occurred in relation to the device shall be reported to LGC Clinical Diagnostics Technical Support and, if in use in the EU, the competent authority of the Member State in which the incident occurred.

Date	Description of Change
June 2025	Initial Release

Refractrol™ SP

Serum Protein Reference Controls
For use on Refractometers



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Legend of all symbols used in LGC product labeling



Upper limit of temperature



Temperature limitation



Authorized Representative in
the European Community



Biological risks



Use By



In Vitro Diagnostic Medical Device



Negative control



Catalogue number



Consult instructions for use



Positive control



Batch code



Manufacturer



Control



Highly Flammable



Toxic by inhalation, in contact
with skin and if swallowed



Health Hazard



Single Use



Importer