



SYPHILIS HEALTH CHECK

Control Set

For *in vitro* diagnostic use only.

INTENDED USE

The Syphilis Health Check Control Set is intended for use with the Syphilis Health Check Treponemal Antibody test as a quality control material to monitor the test performance. The controls should be tested in the same manner as patient samples.

To be used as part of a Quality Control program as defined in the Syphilis Health Check test Package Insert.

CONTENTS

The Syphilis Health Check Control Set contains syphilis antibodies positive and negative controls diluted in pooled human serum which has been tested and found negative for anti-HIV, anti-HCV and HIV-1 antigen.

- 1 plastic dropper containing 0.5 mL of Syphilis Positive control*.
- 1 plastic dropper containing 0.5 mL of Syphilis Negative control*.

*Contains 0.05% NaN₃.

STORAGE CONDITIONS

Store refrigerated at +2°C to +8°C until expiration date printed on label. Do not use after the expiry date. Allow to warm to room temperature before use in the assay. Refrigerate after use. Controls are stable for 12 months after first opening when stored at +2°C to +8°C between each use. Do NOT Freeze.

MATERIALS REQUIRED BUT NOT PROVIDED

Syphilis Health Check (SHC) test kit

INSTRUCTIONS FOR USE

1. The Syphilis Health Check Positive and Negative controls are liquid and are ready to use.
2. Bring to room temperature before use.
3. Add ONE drop (25 µL) of the control (Positive or Negative) into the sample well of the cassette and proceed in the same way as for a patient's sample by adding 4 drops of the Buffer Diluent (included in the SHC test kit).
4. Read the result after 10 minutes. The result can be read up to 15 minutes.

PLEASE NOTE: Do not read after 15 minutes.

WARNINGS AND PRECAUTIONS

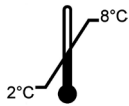
WARNING: Potentially Infectious Material

Treat as if capable of transmitting infection.

Use caution when handling material of human origin. Consider all samples potentially infectious. Although the human serum used in the preparation of these controls was tested and found negative for anti-HIV, anti-HCV and HIV-1 antigen with FDA approved methods, no test method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV 1+2) or other infectious agents are not absent. Handle, use, store and dispose of solid and liquid waste from samples and test components, in accordance with procedures defined by appropriate national biohazard safety guideline or regulation (e.g. CLSI document M29 -Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline (Clinical and Laboratory Standards Institute)

LIMITATIONS

The Syphilis Health Check Positive and Negative controls are intended for supplementing laboratory quality control procedures and are not for use in validating test performances.



Temperature limitations



Consult Syphilis Health Check Package Insert for use and interpretation of results.



For *in vitro* diagnostic use



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Manufactured for Diagnostics Direct, LLC

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