References

1. FAQs on Viral Transport Media During COVID-19
   fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-viral-transport-media-during-covid-19

2. CDC preventing transmission of infectious agents in healthcare settings guidelines;
   cdc.gov/infectioncontrol/guidelines/isolation

Symbol glossary

biomeddiagnostics.com/l/symbol-glossary

Document Revision History

Rev. A, July 2020

Included ISO 13485 statement; removed conductivity specification and corrected pH range; specified not to store frozen; identified SARS-CoV-2 strain; included FAQS reference; corrected "LightCycle" typo.

Rev. NEW, July 2020

New Document

Manufactured by:
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100-612 IFU Saline Solution (0.85%) Rev. A (07/2020)

BIOMED DIAGNOSTICS

Saline Solution (0.85%)

Saline solution for viral specimens

REF 11-612-002 Σ 50

REF 11-612-003 Σ 150

Not available in all countries; please inquire.

For In Vitro Diagnostic Use
Instructions must be carefully followed.

IVD 2°C 25°C

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Certificate
of Analysis

Introduction

Intended Use

Saline Solution (0.85%) is a saline solution for viral specimens.

Description and Principle

The Saline Solution (0.85%) is an isotonic solution, manufactured in compliance with ISO 13485:2016 standards. It is intended to be inoculated with nasopharyngeal (NP) or oropharyngeal (OP) synthetic fiber swab specimens (Not provided, see "Procedure" section for details), to be analyzed in the laboratory with validated qRT-PCR assays. This Saline Solution (0.85%) has been validated for the detection of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes COVID-19 disease in humans.[1,2] The use of this device for other viral specimens is the responsibility of the end user including the validation thereof.

When used according to the instructions for use, the Saline Solution (0.85%) ensures a non-replicating competent status of SARS-CoV-2 (COVID-19) thereby preserving viral RNA genome integrity of the virus. The Saline Solution (0.85%) is aseptic and does not contain bacteria or fungi growth-inhibition agents. Therefore, specimen should be handled under suitable conditions that do not encourage growth of these microbes. From the site of collection to downstream laboratory nucleic acid testing (e.g., qRT-PCR), the Saline Solution (0.85%) is intended to aid in the process of collection and transport of human clinical specimens that contain the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is the responsibility of the end user to validate the use of this device for viral specimens other than described here.

The Saline Solution (0.85%) is validated to be compatible with the identification of SARS-CoV-2 using qRT-PCR technology by:

- Aiding the safe transport and preservation of the specimen.
- Viral specimen stored in the Saline Solution (0.85%) at room temperature (18–25 °C) for 72 hours is compatible with downstream qRT-PCR tests.
- Compatible with approved nucleic acid extraction and qRT-PCR tests.

Reagents and Appearance

The Saline Solution (0.85%) in polypropylene tubes appears clear and contains 8.5 g Sodium Chloride per liter of deionized water. Post-production pH of the solution is 6.5 ± 1.0 at 25°C.

Precautions, Safety and Disposal

Read the Safety Data Sheet (SDS) and follow the handling instructions. Wear appropriate protective eyewear, clothing and gloves.

Do not use if package is damaged or leaking.

All specimens should be handled according to the CDC preventing transmission of infectious agents in healthcare settings guidelines[2]
cdc.gov/infectioncontrol/guidelines/isolation/index.html

Once the tube has been inoculated and resealed, re-open only in a biological safety cabinet. Prior to disposal, sterilize tubes by autoclaving at 121°C for 20 minutes or through another suitable means of sterilization.

Any serious incident that occurs in relation to this device shall be reported to the manufacturer and the competent authority, as required, of the country in which the user and/or the patient is established.

Storage

Do not store frozen. Keep away from direct light and heat exposure. Do not use expired solution. Do not use the solution if it appears to be damaged, leaking or the solution appears to be cloudy or evaporated.

Procedure

Key Notes Regarding Specimen Collection

Materials Provided

- Saline Solution (0.85%)

Materials Required but Not Provided

Swabs: Use synthetic fiber nylon or Dacron® swab tips with plastic or aluminum shafts only, as recommended.[1] To be used with Nasopharyngeal (NP) or Oropharyngeal (OP) specimens.

Sample: Please see Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) **cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.** The use of this device for other sample/specimen types is the responsibility of the end user.

Handling conditions

The Saline Solution (0.85%) is designed to aid the safe transport of inoculated specimen suspected to contain the SARS-CoV-2 virus. Inoculated tubes should be used for testing or transferred to 2–8°C within 72 hours after inoculation.[2]

It is possible to keep the tube at room temperature (18-25°C) for up to 72 hours. However, please note that the compatibility of the specimen with qRT-PCR testing beyond 72 hours at 18–25°C should be evaluated by the user.

Quality Control

This product is aseptic and has been tested and meets the CLSI (formerly NCCLS) Approved Standard for commercially prepared media (M22-A3). At the time of manufacture, quality control testing is performed on each lot of Saline Solution (0.85%) for verification of sterility. Refer to the CoA for lot-specific information.

Limitations

- Performance of the Saline Solution (0.85%) may be impacted by extreme temperatures and repeated freeze and thaw cycles.
- The use of Saline Solution (0.85%) for uses other than described here shall be evaluated by the end user.
- The use of swabs with wooden or calcium alginate components has not been tested with the Saline Solution (0.85%) and should not be used.
- The use of this product with any diagnostic test should be evaluated and tested by the end user.
- This product is not a replacement for viral cell culture medium.

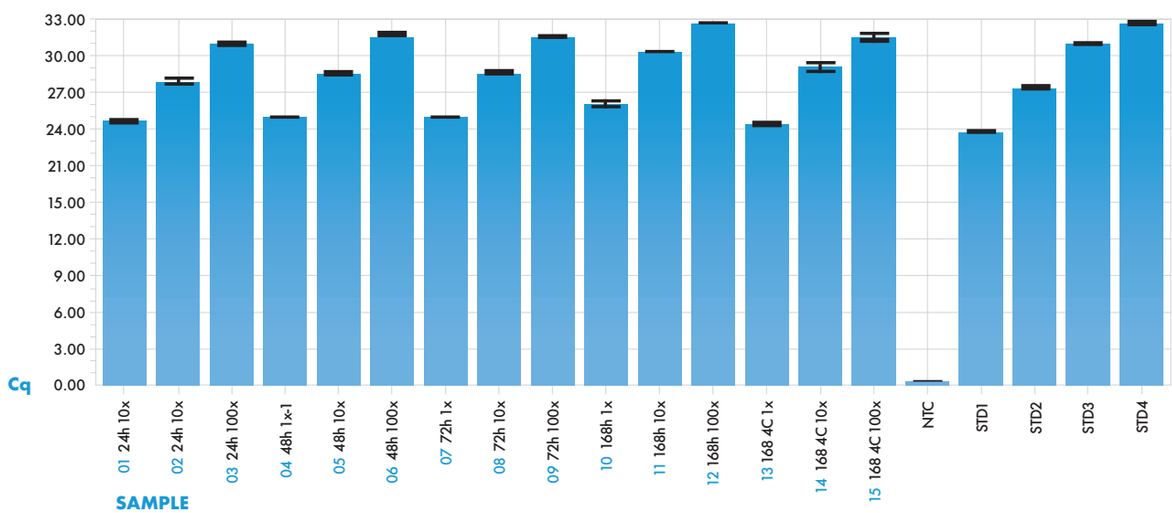
Performance Characteristics

This test was performed to evaluate the Biomed Saline Solution (0.85%) by detection of heat inactivated cell lysate from SARS-Cov-2 (ATCC® VR-1986HK™) infected cells, after RNA was isolated using the QIAamp® Viral RNA Mini Kit (QIAGEN®). Detection of the isolated SARS-Cov-2 RNA was by qRT-PCR using New England Biolabs® OneTaq® One-Step RT-PCR kit and run on a Roche® Lightcycler® 96 with EvaGreen® (Biotium®) detection from samples after storage of viral lysates in Saline Solution (0.85%) at 24, 48 and 72 hours at room temperature (25°C). Synthetic RNA standard (BEI Resources) at 2.9 x 10^8 was serially (10-fold) diluted for the standard (STD) in the amplification reaction.

The assay results demonstrate consistent amplification and Cq quantification of the nCov-2 N gene (using the N1 CDC primer) in the solution after incubations.

In addition, excellent dilution linearity is demonstrated across all samples and replicates (See Figure 1) indicating consistency in the performance of the solution Saline Solution (0.85%) replicate samples and incubation time. This data indicates that the Biomed ISO 13845 manufactured Saline Solution (0.85%) does not negatively interfere with the qRT-PCR detection of Sars-Cov-2 viral nucleic acid materials after incubation at room temperature 25°C for 72 hours. A delay in amplification signal was observed after 168-hour (7 days) incubation at 25°C, probably due to specimen degradation. However, incubation at 4°C for 168 hours (7 days) did not negatively interfere with the qRT-PCR performance. In conclusion, the result indicates that the Saline Solution (0.85%) is compatible with the designated viral specimen inoculation, nucleic acid extraction and qRT–PCR assay when used as described herein.

Fig. 1: Cq values for triplicate time- course dilution samples and controls



All samples shown are means from triplicate assays, with error bars indicating the arithmetic error for Cq shown. The performance of the qRT-PCR reaction assessed with standard curves indicated R^2 of 0.98, Efficiency of 114%, and Slope of -3.033. All the values fall within acceptable quantitative PCR ranges.