

SARS-CoV-2 External Control Panel

REF 719

INTENDED USE

The ZEUS SARS-CoV-2 External Controls are defibrinated human plasma samples to be used as unassayed quality control sera for serology tests for antibody to SARS-CoV-2 virus.

SIGNIFICANCE AND BACKGROUND

These two positive and two negative specimens may be used as external controls for various immunoassays. They were prepared from human plasma and have been previously characterized in their performance on multiple serology tests. The two positive specimens contain antibody at levels that would be abnormally high. The two negative specimens do not contain abnormal levels of antibody to the SARS-CoV-2 virus.

PACKAGE COMPONENTS

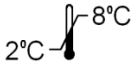
Materials Provided:

1. Two specimens that are positive for antibody to the SARS-CoV-2 virus - 0.4 mL per vial.
2. Two specimens that are negative for antibody to the SARS-CoV-2 virus - 0.4 mL per vial

PRECAUTIONS

1. **NOTE: Two of these plasma samples came from patients who were diagnosed with COVID-19 by PCR.** It is unknown if these plasma samples contain viable virus; however, as with any human biological specimen, **they should be handled with extreme care, as if they are capable of transmitting COVID-19.**
2. Follow normal precautions exercised in handling laboratory reagents. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Dispose of waste observing all local, state, and federal laws.
3. These external controls are **potentially biohazardous materials**. Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, handle these products at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories": Current Edition; and OSHA's Standard for Bloodborne Pathogens.

STORAGE CONDITIONS

	Defibrinated Human Plasma Samples
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PROCEDURE

These specimens may be used and analyzed the same as any other patient sample, in accordance with the instructions provided with the immunoassay in question. These samples are stable until the date specified on the vial label when stored at 2 - 8°C.

EXPECTED RESULTS

As labeled, two of these specimens should generate a positive result on the SARS-CoV-2 immunoassay and two of the specimens should generate a negative result on the SARS-CoV-2 immunoassay.