



## IMMUNOASSAY CONTROL FOR POC, LIQUID

Product	Lot Number	Expiration Date
Immunoassay Control for POC, Kit	4800F001	1 year after DOM
Immunoassay Control for POC, Level 1	4801F001	1 year after DOM
Immunoassay Control for POC, Level 2	4802F001	1 year after DOM

### INTENDED USE

**CONE BIOPRODUCTS POC Control Kits** are human Liquid assayed serum samples, used to validate analyzer performance according to CLIA guidelines.

### SUMMARY AND PRINCIPLE

**CONE BIOPRODUCTS POC Control Kits** are provided at two levels ranging across the analytes reportable range to assist in validation of Analyzer recovery Control procedures. The use of independent quality control sample materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control samples are available to allow performance monitoring within the clinical range.

### REAGENT

**CONE BIOPRODUCTS POC Control Kits** are prepared from human plasma to which stabilizers are added. The product is in liquid form for user convenience. No additional reconstitution is required. The control samples are in a prepackaged liquid form to avoid potential error or contaminate being introduced during reconstitution.

### STORAGE AND STABILITY

Unopened **CONE BIOPRODUCTS POC Control Kits** are stable until the expiration date when stored frozen at -20°C. Upon opening containers, product is stable for 30 days when stored at 2-8°C in tightly closed containers.

### WARNING

Biological source material. Treat as potentially infectious. Each serum/plasma donor unit used in manufacturing this product was tested by FDA accepted methods and found non-reactive or negative for Hepatitis B Surface Antigen (HbsAg), HCV antibodies, and HIV-1/2 antibodies. This product may contain other human or animal source materials for which there are no approved tests and should be considered as potentially infectious for Hepatitis B (HBV), Hepatitis C (HCV), HIV-1, HIV-2, HTLV-I, HTLV-II, as well as any other infectious agent, and handled with the same precautions used in handling patient specimens.

### PROCEDURE

**CONE BIOPRODUCTS POC Control Kits** should be treated in the same manner as patient samples in accordance with instructions for determination method being used. Frozen control samples should be thawed at room or refrigerator temperature and mixed by gentle inversion prior to use.

### LIMITATIONS

Different values from those obtained with reagents available at the time of assay may be obtained as a result of changes in manufacturer's reagents or lot-to-lot reagent variability. **CONE BIOPRODUCTS POC Control Kits** should not be used past its expiration date or after improper handling. Microbial contamination will affect performance of this product.

### ANALYTE VALUES

In accordance with good laboratory practices, each laboratory should establish its own analyte means and acceptable performance ranges.

### Assignment of Values

The mean values printed on the circular were derived from replicate analyses and are specific for this lot of Liquid Assayed Control Samples.

### SPECIFIC PERFORMANCE CHARACTERISTICS

**CONE BIOPRODUCTS POC Control Kits** are manufactured in accordance with industry guidelines and standards. To perform as intended, the control Kits requires proper storage and handling as described in this package insert.

## Assigned Values (Representative Values)

POC analyzer Control kit Lot # 4800F001 containing:  
Level 1 (LOT# 4801F001); Level 2 (LOT# 4802F001)

### For In Vitro Diagnostic Use

ANALYTE	METHOD	UNITS	4801F001	4802F001
			Level 1 Mean	Level 2 Mean
PSA	NanoEntek POC	ng/mL	3.79	12.73
TSH	NanoEntek POC	uIU/mL	1.52	8.90
Testosterone	TOSOH AIA-360	ng/mL	0.63	4.01
Free-T4	TOSOH AIA-360	ng/mL	0.77	2.27