

FREND Immunoassay Control Kits
Part No: NOD17026-300 (12Vials) or NOD17021-300 (2 Vials)

	Lot Number	Expiration Date
NOD® FREND Immunoassay Control Kit	6360A26001	2027-09-30
NOD® FREND Immunoassay Control Level 1	6361A26001	2027-09-30
NOD® FREND Immunoassay Control Level 2	6362A26001	2027-09-30

INTENDED USE

NOD® FREND Immunoassay Control Kits are human Liquid assayed serum samples, used to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

SUMMARY AND PRINCIPLE

The use of independent quality controls 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. Three levels of control are available to allow performance monitoring within the clinical range.

REAGENT

NOD® FREND Immunoassay 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 NOD® FREND Immunoassay Control Kits are stable until the expiration date when stored frozen at ≤-11°C unopened. 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

NOD® FREND Immunoassay 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. NOD® FREND Immunoassay 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 on the FREND immunoassay Analyzer and are specific for this lot of Liquid Assayed Control Samples.

SPECIFIC PERFORMANCE CHARACTERISTICS

NOD® FREND Immunoassay Control Kits are manufactured in accordance with industry guidelines and standards. To perform as intended, the Control and control Kits requires proper storage and handling as described in this package insert.

Assigned Values (Representative Values)

**NOD® FREND IMMUNOASSAY CONTROL kit Lot # 6360A26001 containing:
 Level 1 (LOT # 6361A26001) and Level 2 (LOT # 6362A26001)**

For In Vitro Diagnostic Use

ANAYLTE		FT4 (ng/dL)	PSA (ng/mL)	Testosterone (ng/dL)	TSH (mIU/L)	¹ Vitamin D (ng/mL)
Level 1 6361A26001	Mean	1.79	1.35	261.4	0.82	25.2
Acceptable Range		0.58 – 3.00	0.41 – 2.29	127.3 – 395.4	<0.06 – 1.73	<13.0 – 40.3
CV (%)		33.7%	34.7%	25.6%	36.9%	30.0%
Level 2 6362A26001	Mean	2.92	15.99	900.2	10.85	47.9
Acceptable Range		1.27 – 4.56	9.38 – 22.59	497.8 – 1303	6.82 – 14.88	26.0 – 69.8
CV (%)		28.2%	20.7%	22.3%	18.6%	22.9%

¹Values Assignments used in the table above were performed by NanoEntek
¹Notice: It is recommended to use the Vitamin D in the "Patient" mode

