

	Lot Number	Expiration Date
<b>NOD</b> <sup>®</sup> FREND VERIFICATION Kit	6210A25001	2027-12-31
<b>NOD</b> <sup>®</sup> FREND VERIFICATION Sample 1	6211A26001	2028-04-30
<b>NOD</b> <sup>®</sup> FREND VERIFICATION Sample 2	6212A25001	2027-12-31
<b>NOD</b> <sup>®</sup> FREND VERIFICATION Sample 3	6213A25001	2027-12-31
<b>NOD</b> <sup>®</sup> FREND VERIFICATION Sample 4	6214A26001	2028-04-30
<b>NOD</b> <sup>®</sup> FREND VERIFICATION Sample 5	6215A26001	2028-04-30

**INTENDED USE**

**NOD**<sup>®</sup> **FREND Verification Kits** are human Liquid assayed serum samples, used to validate analyzer performance according to CLIA guidelines. Although CLIA regulations exempts factory calibrated analyzers like the FREND from six-month Calibration Verification, we encourage Lab Directors to consider the practice at their discretion.

**SUMMARY AND PRINCIPLE**

**NOD**<sup>®</sup> **FREND Verification Kits** are provided at five levels ranging across the reportable range of the analytes to assist in validation of Analyzer recovery verification procedures. The use of independent quality verification 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. Five levels of verification samples are available to allow performance monitoring within the clinical range.

**REAGENT**

**NOD**<sup>®</sup> **FREND Verification 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 verification samples are in a prepackaged liquid form to avoid potential error or contaminate being introduced during reconstitution.

**STORAGE AND STABILITY**

Unopened **NOD**<sup>®</sup> **FREND Verification 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**<sup>®</sup> **FREND Verification Kits** should be treated in the same manner as patient samples in accordance with instructions for determination method being used. Frozen verification 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**<sup>®</sup> **FREND Verification 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 Verification Samples.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**NOD**<sup>®</sup> **FREND Verification Kits** are manufactured in accordance with industry guidelines and standards. To perform as intended, the Verification and control Kits requires proper storage and handling as described in this package insert.





**Assigned Values (Representative Values)<sup>1,2</sup>**  
**NOD® FRENDS VERIFICATION kit Lot # 6210A25001 containing:**  
**Sample 1 (LOT# 6211A26001); Sample 2 (LOT# 6212A25001); Sample 3 (LOT# 6213A25001)**  
**Sample 4 (LOT# 6214A26001); Sample 5 (LOT# 6215A26001)**

**For In Vitro Diagnostic Use**

ANALYTE		FT4 (ng/dL)	PSA (ng/mL)	Testosterone (ng/dL)	TSH (mIU/L)	Vitamin D (ng/mL)
Sample 1 6211A26001	Mean	0.75	0.13	47.68	0.31	17.8
Acceptable Range		<0.40 – 1.24	<0.08 – 0.77	<20.00 – 119.8	<0.06 – 1.03	<13.0 – 25.9
Sample 2 6212A25001	Mean	1.00	1.92	101.6	3.00	43.0
Acceptable Range		0.49 – 1.51	1.43 – 2.41	<20.00 – 236.4	1.41 – 4.58	21.7 – 64.4
Sample 3 6213A25001	Mean	1.46	8.21	492.4	10.74	57.2
Acceptable Range		0.84 – 2.08	5.19 – 11.22	258.9 – 725.8	7.73 – 13.74	29.5 – 84.9
Sample 4 6214A26001	Mean	3.21	18.70	1056	21.83	88.1
Acceptable Range		1.66 – 4.76	13.43 – 23.97	743.1 – 1369	15.15 – >25.00	65.9 – >96.0
Sample 5 6215A26001	Mean	4.66	23.79	1352	>25.00	>96.0
Acceptable Range		3.51 – 5.81	15.97 – >25.00	1058 – >1500	18.62 – >25.00	82.8 – >96.0

<sup>1</sup>Note: This material **must** be used exclusively in "PATIENT" Test Mode. Please reference table for expected values.

<sup>2</sup>Values Assignments used in the table above were performed by NanoEntek