NOVA-ONE® DIAGNOSTICS Delivering Innovative Medical Diagnostics Everyday

NOD®/FREND Verification Kit Part No: NOD17051-500

	Lot Number	Expiration Date
NOD® FREND VERIFICATION Kit	**6210A24001**	**2026–10–31**
NOD® FREND VERIFICATION Sample 1	**6211A24001**	**2026–10–31**
NOD® FREND VERIFICATION Sample 2	**6212A24001**	**2026–10–31**
NOD® FREND VERIFICATION Sample 3	**6213A24001**	**2026–10–31**
NOD® FREND VERIFICATION Sample 4	**6214A24001**	**2026–10–31**
NOD® FREND VERIFICATION Sample 5	**6215A24001**	**2026–10–31**

INTENDED USE

NOD® **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® **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® **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 ® **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.

PROCEDURE

NOD® **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® **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® **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.

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.

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(REV 10/11/2024)

Assigned Values (Representative Values)**
NOD® FREND VERIFICATION kit Lot # 6210A24001 containing:
Sample 1 (LOT# 6211A24001); Sample 2 (LOT# 6212A24001); Sample 3 (LOT# 6213A24001)
Sample 4 (LOT# 6214A24001); Sample 5 (LOT# 6215A24001)

For In Vitro Diagnostic Use

ANALYTE		FT4* (ng/dL)	PSA (ng/mL)	Testosterone (ng/dL)	TSH (mIU/L)	Vitamin D (ng/mL)
Sample 1 6211A24001	**Mean**	< 0.40	0.15	< 20.00	< 0.06	< 13.0
Acceptable Range		–	<0.08 – 0.41	–	–	–
Sample 2 6212A24001	**Mean**	< 0.40	1.68	216.3	1.35	39.4
Acceptable Range		0.64 – 0.96	0.24 – 3.11	58.87 – 373.7	<0.06 – 3.00	23.3 – 55.4
Sample 3 6213A24001	**Mean**	2.91	10.51	710.7	11.37	64.7
Acceptable Range		1.84 – 3.98	6.02 – 15.00	334.1 – 1087	6.04 – 16.70	40.1 – 89.3
Sample 4 6214A24001	**Mean**	3.79	18.09	1066	19.57	94.5
Acceptable Range		2.68 – 4.91	13.94 – 22.25	621.0 – >1500	13.47 – >25.00	67.2 – >96.0
Sample 5 6215A24001	**Mean**	4.90	>25.00	1298	>25.00	>96.0
Acceptable Range		3.41 – >6.00	19.55 – >25.00	960.7 – >1500	13.76 – >25.00	91.7 – >96.0

***Note: FT4 could test lower on Level 2 than Level 1. Please reference table for expected values.**
**Values Assignments used in the table above were performed by NanoEntek

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