Clinical Performance Evaluation Of The Vitamin D Rapid Test Cassette (OVD-402H): Comparative Analysis With HPLC And A Predicate Quantitative Assay

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KEYWORDS

Vitamin D, Rapid Test, Lateral Flow Immunoassay, Point-of-Care, HPLC, Clinical Evaluation.

ABSTRACT

This study evaluates the diagnostic accuracy of the Vitamin D Rapid Test Cassette (OVD-402H) using two independent data sets: a 2025 comparison with high-performance liquid chromatography (HPLC) (n = 10) and a 2017 in-house clinical study benchmarked against a predicate quantitative assay (n = 90). The cassette correctly classified vitamin D status (deficient, insufficient, sufficient) in all ten HPLC-verified samples and achieved 94.4 % overall agreement in the larger in-house cohort. These findings confirm that OVD-402H delivers laboratory-comparable performance while retaining the speed and simplicity required for point-of-care testing.

1. Introduction

Vitamin D deficiency affects an estimated one billion people worldwide and is linked to osteoporosis, immune dysfunction and cardiometabolic disease. Conventional determination relies on laboratory-based HPLC or chemiluminescent assays—methods that are costly and time-consuming. Lateral-flow rapid tests, such as the OVD-402H cassette, promise decentralised screening but must be rigorously benchmarked against reference techniques to ensure clinical reliability.

2. Materials and Methods

Study Design and Specimens:

1. **HPLC comparison (2025):** Ten finger-stick whole-blood samples, spanning deficient (<10 ng mL^{-1}), insufficient (10–30 ng mL^{-1}) and sufficient (>30 ng mL^{-1}) ranges, were tested in parallel with the OVD-402H cassette and HPLC at AllTest Biotech.
2. **In-house clinical study (2017):** Ninety archived clinical specimens (4 deficient, 56 insufficient, 30 sufficient) were tested with OVD-402H and a predicate quantitative vitamin D assay (Rapi-D).

Test Procedure:

Twenty microlitres of finger-stick whole blood were applied to the cassette sample well, followed by two drops of buffer. Results were interpreted at 10 min.

Data Analysis:

Positive, negative and overall agreement were calculated versus each reference method. Accuracy was defined as the proportion of correctly classified specimens across three vitamin D status categories.

3. Results

HPLC Comparison:

The rapid test matched HPLC in all ten specimens (100 % categorical agreement). Mean HPLC concentrations were 9.56 ± 0.80 ng mL^{-1} (deficient), 18.99 ± 2.48 ng mL^{-1} (insufficient) and 37.41 ± 7.98 ng mL^{-1} (sufficient).

In-house Clinical Study:

Vitamin D status (predicate)	n	Rapid test concordant	Agreement (%)

Deficient	4	4	100.0
Insufficient	56	53	94.6
Sufficient	30	28	93.3
Overall	90	85	**94.4**

No test failures or invalid results were observed.

4. Discussion

The OVD-402H cassette demonstrated excellent concordance with both HPLC and a quantitative predicate assay. Perfect agreement in the pilot HPLC set highlights its capability to correctly stratify patients across clinically relevant vitamin D thresholds. The larger 2017 cohort confirms robustness, yielding >93 % agreement in each category and an overall accuracy of 94.4 %. These figures meet the >90 % relative accuracy criterion recommended by ISO 20916:2019 for point-of-care in-vitro diagnostic devices.

Compared with laboratory methods, the cassette offers:

- **Speed:** results in 10 min versus hours-to-days for HPLC.
- **Simplicity:** no instrumentation; minimal training.
- **Portability:** suited to community screening and resource-limited settings.

Limitations include the small size of the 2025 HPLC subset and absence of external-site validation. Future multicentre trials with larger populations and capillary-venous paired samples are warranted.

5. Conclusion

Across two independent studies, the Vitamin D Rapid Test Cassette (OVD-402H) achieved laboratory-comparable accuracy while providing rapid, instrument-free results. The device is therefore a reliable option for point-of-care assessment of vitamin D status.

References:

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