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Serum Determinations in SARS COV2 Infection

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Abstract

Purpose

This presentation outlines the technical specifications, procedural guidelines, and clinical performance data for the VIDAS® SARS-CoV-2 IgG II (9COG) assay (pp. 1-2). The test serves as an automated diagnostic aid to evaluate whether an individual has developed a specific humoral immune response following exposure to the SARS-CoV-2 virus or vaccination (pp. 2, 4).

Methodology

The assay utilizes the Enzyme Linked Fluorescent Assay (ELFA) technique, combining a two-stage sandwich enzyme immunoassay with automated fluorescence detection via a specialized Solid Phase Receptacle (SPR) device (pp. 2, 5). The inner wall of the SPR is coated with recombinant receptor-binding domain (RBD) of the viral Spike protein to capture specific IgG antibodies from human serum or plasma (pp. 2, 7). Alkaline phosphatase-labeled anti-human IgG antibodies and a 4-methylumbelliferyl phosphate substrate are then introduced to generate a measurable fluorescent signal (pp. 6, 11).

Performance and Results

The automated analysis delivers semi-quantitative index results within approximately 27 minutes (pp. 2, 24). The test is highly precise and exhibits a wide linear range between 0.40 and 17.00 index values, with a determined cut-off value of 1.00 index equivalent to 20.33 BAU/ml relative to the first WHO international standard (pp. 27, 29, 31). Clinical evaluations demonstrate an overall internal specificity of 99.9% (p. 39). Clinical sensitivity is strongly correlated with time elapsed post-infection, rising from 45.3% within the first 7 days following a positive PCR result to 96.6% after 16 or more days (p. 40). Cross-reactivity studies against a panel of 261 potentially interfering infectious conditions verified high analytical specificity with minimal cross-reactivity (pp. 35-36).

Conclusion

The VIDAS® SARS-CoV-2 IgG II assay provides a highly efficient, reliable, and standardized solution for clinical laboratories to quantify anti-RBD Spike protein IgG antibodies, facilitating accurate long-term humoral immunity assessment (pp. 2, 4).
Keywords: SARS-CoV-2, Immunoglobulin G (IgG), Enzyme Linked Fluorescent Assay (ELFA), Receptor Binding Domain (RBD), Spike Protein, VIDAS Automation, Humoral Immunity, Clinical Sensitivity, Analytical Specificity