COVID-19 Diagnostic Testing

Technical Screening Serological Assays (ELISA, antigen and antibody tests)

Name of the device	**ADVIA CENTAUR SARS-COV-2 TOTAL (COV2T) / ADVIA CENTAUR SARS-COV-2 TOTAL QUALITY CONTROL (COV2T QC)**
Manufacturer	**SIEMENS HEALTHCARE DIAGNOSTICS INC.**
Application #	**316549**
Technology	**Antibody**
Test Setting	**Lab**
DED Screener	**Ian Aldous**

Notes to reviewer	**FDA approved**

	Guidance	Acceptable	Comment
Device Description	**Type of technology:** - ELISA, Lateral-Flow, antigen detection, antibody detection. - qualitative, quantitative - instrumentation required **Sample type / collection methods**: Fingerstick samples require additional validation for POC use (see below) **Testing setting:** Laboratory / Point of Care **Calibrator and controls** (value assignment) **Antigen source:** what it is and what is the source. **Intended use statement assessed during review**	Y	
Analytical Sensitivity	**There is no requirement for LoD for serological assay**. Diagnostic Sensitivity demonstrated in clinical studies is more relevant. **For antigen tests, LoD is required.** Relative analytical sensitivity of ELISA can be assessed by end-point dilution analysis which indicates the dilution of serum in which antibody is no longer detected. Should be requested at screening only if nothing is provided (quality of information assessed during review)	Question 2	
Cut Off	How the cutoff was established	Y	
Hook effect	Applicable for sandwich immunometric assays	Y	
Sample matrix	**Equivalence between sample types/Matrix equivalency studies** • POC needs data for fingertip sample type. • If no data for each sample type, a specimen equivalency study is requested • Patient serum used to validate the tests: number and variety of sera (assessed during review). • Validation of anticoagulants **For antigen test**: Equivalency between swabs recommended if all the studies were done with one swab	Y	
Interference and Cross Reactivity	• **Endogenous substances** including : Hb, bilirubin, Proteins, TG, HAMA, RF, Total IgG, Total IgM. • **For antigen tests**, either naturally present in respiratory specimens or artificially introduced into the nasal cavity or nasopharynx • **Exogenous:** Common medication • **Cross-reactivity** with non-targeted commensal and pathogenic microorganisms. **Antigen assay**: in silico analysis alone is not acceptable. If wet testing is also provided only wet testing results should be listed in package insert. **For antibody assays : Class specificity** : For IgM assays, to determine if reactivity with SARS-CoV-2 specific IgG is a potential assay interferent and vice versa for IgG assays. Detection of total Ab detection: no need for class specificity	Y	
Precision	Evidence of repeatability	Y	

Seroconversion	Seroconversion panel testing, ***if available***.		
Stability	**Description of stability test plan** • reagent stability studies do not need to be completed at the time of IO issuance, however the study design should be agreed upon during review and the stability studies started immediately following authorization	Y	
Robustness	Use variation : sample and reagent volume, operating temperature and humidity, reading time and illumination (visual reading)	Y	
Clinical Evaluation	• A minimum of 50 positive clinical samples and 200 negative clinical samples is required for clinical evaluation. • **Comparator assay (RT-PCR) should be authorised**, either by HC, or EUA from US, or WHO EUL. • **ELISA:** reference range study with a minimum of 500 samples • **POC intended use**: Performance data required for each sample type. • **Timing of the collection of positive** samples (infection time)	Y	
Point of Care	**Near patient studies** performed in clinical setting by intended users. Minimum of 9 operators and questionnaire to assess IFU clarity.	n/a	
Labeling	**Instructions for use** **Reagent labels** Intended Use Statement will be assessed during review	Y	
Quality	• **QMS certificate provided?** • **Evidence of lot release programme**	Y	