

**2.7.1 SUMMARY OF BIOPHARMACEUTIC STUDIES AND ASSOCIATED
ANALYTICAL METHODS**

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SUMMARY OF BIOPHARMACEUTIC STUDIES AND ASSOCIATED ANALYTICAL METHODS

COVID-19 diagnostic and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) human serological assays were utilized in support of the Phase 1 and 2/3 clinical evaluation of BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048), an investigational vaccine intended to prevent COVID-19, which is caused by SARS-CoV-2. Assay descriptions and summaries of the qualification or validation studies performed for each assay method are included in Section 5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies or Section 5.3.5.1 Study Reports and Related Information of Controlled Clinical Studies Pertinent to the Claimed Indication. Per communications with the Center for Biologics Evaluation and Research, primary endpoint assays used in the Phase 2/3 studies are validated; whereas assays used for exploratory endpoints are qualified.

Table 1 lists each bioanalytical method, the location of its corresponding assay summary, and the assay parameters, including limit of detection (LOD), the lower and upper range, and/or the assay's lower limit of quantitation (LLOQ).

Table 1. Summary of Bioanalytical Methods for Human Studies

Bioanalytical Method	Title and Section Location	Assay Parameters			
		LOD	Lower Range	Upper Range	LLOQ
Cepheid Xpert® Xpress SARS-CoV-2 ^a	5.3.1.4 VR-MVR-10080	0.01 FFU/mL	N/A	N/A	N/A
Roche Elecsys SARS-CoV-2 N-Binding Antibody Assay ^a	5.3.1.4 VR-MVR-10081	N/A	N/A	N/A	N/A
Single-plex Direct Luminex Assay for Quantitation of SARS-CoV-2 S1-binding IgG in Human Serum ^b	5.3.1.4 VR-MQR-10211	N/A	0.002533 U/mL well concentration	0.128000 U/mL well concentration	1.2665 Dilution adjusted U/mL
Single-plex Direct Luminex Assay for Quantitation of SARS-CoV-2 RBD-binding IgG in Human Serum ^b	5.3.1.4 VR-MQR-10212	N/A	0.002301 U/mL well concentration	0.128000 U/mL well concentration	1.1505 Dilution adjusted U/mL

Table 1. Summary of Bioanalytical Methods for Human Studies

Bioanalytical Method	Title and Section Location	Assay Parameters			
		LOD	Lower Range	Upper Range	LLOQ
mNeonGreen SARS-CoV-2 Microneutralization Assay ^b	5.3.1.4 VR-MQR-10214	20	N/A	N/A	N/A
mNeonGreen SARS-CoV-2 Microneutralization Assay ^{a,c}	5.3.1.4 VR-MVR-10083	20	41	3187	41
ELISpot Assay ^b	5.3.5.1 BNT 162-01, Appendix 16.1.14 R-20-0244	N/A	N/A	N/A	N/A
	5.3.5.1 BNT 162-01, Appendix 16.1.14 GA-RB-022-01A	N/A	N/A	N/A	N/A
Intracellular Cytokine Staining (ICS) for BNT162b1 ^b	5.3.5.1 BNT 162-01, Appendix 16.1.14 R-20-0235	N/A	N/A	N/A	N/A
Intracellular Cytokine Staining (ICS) for BNT162b2 ^b	5.3.5.1 BNT 162-01, Appendix 16.1.14 R-20-0241	N/A	N/A	N/A	N/A

a. Validation performed on method

b. Qualification performed on method

c. NT50 ranges shown.

Abbreviations: FFU = focus forming units; ICS = intracellular cytokine staining; LOD = limit of detection; LLOQ = lower limit of quantitation; N/A = not applicable; NT = neutralizing titer; U = units