

16.1.10 Documentation of Interlaboratory Standardization Methods and Quality Assurance Procedures if Used

The following central laboratory was used:

PPD Global Central Laboratory
2 Tesseneer Drive
Highland Heights, KY 41076-9167
United States

Laboratory ranges are provided in [Listings 16.2.8.1, 16.2.8.2, 16.2.8.3 and 16.2.8.4](#).

A [memorandum dated 29 May 2020](#) is provided on the following pages.

Memorandum

Date: 29-May-2020

Re: PPD GCL Laboratory normal ranges

Protocol: mRNA-1273-P201 A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

Section 7.2 of the above mentioned protocol (Appendix 2) includes Toxicity Grading Scale Tables for protocol-specified laboratory parameters based on Guidance for industry – Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials; tables for clinical abnormalities (DHHS 2007).

Section 7.2 of the protocol includes statement that the laboratory values provided in the tables serve as guidelines and are dependent upon institutional normal parameters. Institutional normal reference ranges should be provided to demonstrate that they are appropriate.

For any laboratory abnormalities, grading only occurs if the values reside outside of the normal values established by the clinical laboratory.

The purpose of this document is to summarize the normal ranges of Global Central Laboratory at PPD as well as associated toxicity grading for each laboratory parameter.

The actual values provided in the table below will be used for subjects screening (as specified in inclusion and exclusion criteria) and for assessment of any associated laboratory abnormalities during the study period. For values labeled as “No Change” in the table below, the Toxicity Grading Scale Tables for protocol-specified laboratory parameters based on Guidance for industry – Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials; tables for clinical abnormalities (DHHS 2007), will be utilized to assign grade levels for each specific analyte.

(b) (6)

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Moderna Inc., Clinical Trial Manager

Cc: Nadia Hattingh, Project Manager, PPD

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Table for Study-specific normal ranges and associated laboratory abnormalities

ANALYTE	PPD Normal Range ¹	Grade 1	Grade 2	Grade 3	Grade 4
Hemoglobin (female) (g/dL)	11.0 – 15.5	(Remove standard)* Need to Keep Hemoglobin (Female)-Baseline Change Hemoglobin (Male)-Baseline Change	No Change	No Change	No Change
Hemoglobin (male) (g/dL)	12.5 – 17.0	(Remove standard)* Need to Keep Hemoglobin (Female)-Baseline Change Hemoglobin (Male)-Baseline Change	No Change	No Change	No Change
Prothrombin Time – Increase Factor	9.4 – 12.5	>1X ULN - ≤1.1X ULN	No Change	No Change	No Change
PTT – Increase Factor	25.1 – 36.5	>1X ULN - ≤1.2x ULN	No Change	No Change	No Change
WBC increase (cell/mm ³)	3,700 – 11,000	11,001-15000 (Will appear as 11 – 15 (x 10 ³ /uL) in the database)	No Change	No Change	No Change
WBC decrease	3,700 – 11,000	2,500-3500 (Will appear as 2.5-3.5	No Change	No Change	No Change

(cell/mm ³)		(x 10 ³ /uL) in the database)			
Lymphocytes decrease (cell/mm ³)	900 – 3,600	750-899 (Will appear as 0.75-0.899 (x 10 ³ /uL) in the database)	No Change	No Change	No Change
Neutrophils (cell/mm ³)	1,700 -7,900	1,500-1,699 (Will appear as 1.5-1.7 (x 10 ³ /uL) in the database)	No Change	No Change	No Change
Eosinophils (cell/mm ³)	0 -800	801-1,500 (Will appear as 0.8-1.5 (x 10 ³ /uL) in the database)	No Change	No Change	No Change
Platelets decreased (cell/mm ³)	163,000-375,000	125,000-162,999 (Will appear as 125-163 (x 10 ³ /uL) in the database)	No Change	No Change	No Change

¹ Normal ranges of Global Central Laboratory, PPD

² Toxicity Grades are defined based on normal ranges and according to Guidance for industry – Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials; tables for clinical abnormalities (DHHS 2007).

*Grade 1 hemoglobin values have been removed and instead PPD GCL normal ranges will take precedent in determining toxicity at screening.