

**CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION**

LABORATORY NAME AND ADDRESS
COVANCE CENTRAL LABORATORY SERVICES
INC
8211 SCICOR DR
INDIANAPOLIS, IN 46214-2985

CLIA ID NUMBER
15D0647217

EFFECTIVE DATE
04/28/2019

LABORATORY DIRECTOR
ANAGH VORA M.D.

EXPIRATION DATE
04/27/2021

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Karen W. Dyer

Karen W. Dyer, Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

214 Certs2_052620

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
HISTOCOMPATIBILITY (010)	07/17/2007	HISTOPATHOLOGY (610)	07/15/2013
BACTERIOLOGY (110)	09/14/1995	CYTOGENETICS (900)	12/24/2018
MYCOBACTERIOLOGY (115)	09/14/1995		
MYCOLOGY (120)	09/14/1995		
PARASITOLOGY (130)	09/14/1995		
VIROLOGY (140)	09/14/1995		
SYPHILIS SEROLOGY (210)	09/14/1995		
GENERAL IMMUNOLOGY (220)	09/14/1995		
ROUTINE CHEMISTRY (310)	09/14/1995		
URINALYSIS (320)	09/14/1995		
ENDOCRINOLOGY (330)	09/14/1995		
TOXICOLOGY (340)	09/14/1995		
HEMATOLOGY (400)	09/14/1995		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER. FDA-CBER-2021-5683-1072171
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



COLLEGE of AMERICAN
PATHOLOGISTS



The College of American Pathologists
certifies that the laboratory named below

Covance Central Lab Services, LP
Main Laboratory
Indianapolis, Indiana
Anagh Vora, MD

CAP Number: 2926401
AU-ID: 1189428
CLIA Number: 15D0647217

has met all applicable standards for accreditation and is hereby accredited by the
College of American Pathologists' Laboratory Accreditation Program. Reinspection
should occur prior to December 19, 2021 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership,
or location and assumes that all interim requirements are met.

Chair, Accreditation Committee

President, College of American Pathologists

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Project: 522472

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
Hy'sLaw2.2		Both	0Y	999Y	ADC4996=Criteria ADC7567=Potentia	Criteria M Potential	HY H1						
TB ALT Nrm		Both	0Y	999Y	ADC7008=G3 ADC7009=G2 ADC7010=G1 ADC7056=G4	G3 G2 G1 G4	G3 G2 G1 G4						
TB AST Nrm		Both	0Y	999Y	ADC7008=G3 ADC7009=G2 ADC7010=G1 ADC7056=G4	G3 G2 G1 G4	G3 G2 G1 G4						
TB ALT E1v		Both	0Y	999Y	ADC7008=G3 ADC7009=G2 ADC7010=G1 ADC7056=G4	G3 G2 G1 G4	G3 G2 G1 G4						
TB AST E1v		Both	0Y	999Y	ADC7008=G3 ADC7009=G2 ADC7010=G1 ADC7056=G4	G3 G2 G1 G4	G3 G2 G1 G4						
Eosinophil		Female	0D	4D	>0.64 >1.50 >5.00	>0.64 >1.50 >5.00	G1 G2 G3						
			4D	8D	>0.64 >1.50 >5.00	>0.64 >1.50 >5.00	G1 G2 G3						
			8D	15D	>0.64 >1.50 >5.00	>0.64 >1.50 >5.00	G1 G2 G3						
			15D	31D	>0.64 >1.50 >5.00	>0.64 >1.50 >5.00	G1 G2 G3						
			31D	61D	>0.64 >1.50 >5.00	>0.64 >1.50 >5.00	G1 G2 G3						
			61D	180D	>0.64 >1.50 >5.00	>0.64 >1.50 >5.00	G1 G2 G3						
			180D	2Y	>0.64 >1.50 >5.00	>0.64 >1.50 >5.00	G1 G2 G3						
			2Y	6Y	>0.64	>0.64	G1						

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive			
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag	
Eosinophil	Continued	Male		12Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
				18Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
				999Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			0D	4D		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			4D	8D		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			8D	15D		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			15D	31D		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			31D	61D		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			61D	180D		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			180D	2Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			2Y	6Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			6Y	12Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			12Y	18Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
			18Y	999Y		>1.50	>1.50	G2						
						>5.00	>5.00	G3						
					>0.64	>0.64	G1							
Platelets		Female	0D	1D		<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
			1D	8D		<141	<141	G1						
						<25	<25	G4						
						<100	<100	G3						

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
Platelets	Continued	Male	0D	1D	<125	<125	G2						
					<141	<141	G1						
					<25	<25	G4						
					<100	<100	G3						
					8D	15D	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					15D	31D	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					31D	4M	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					4M	7M	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					7M	2Y	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					2Y	3Y	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					3Y	6Y	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					6Y	12Y	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					12Y	60Y	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					60Y	999Y	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				
					8D	15D	<125	<125	G2				
							<141	<141	G1				
							<25	<25	G4				
							<100	<100	G3				

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive			
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag	
Platelets	Continued				<100	<100	G3							
					<125	<125	G2							
					<141	<141	G1							
			15D	31D	<25	<25	G4							
					<100	<100	G3							
					<125	<125	G2							
					<141	<141	G1							
				31D	4M	<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
						<141	<141	G1						
				4M	7M	<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
						<141	<141	G1						
				7M	2Y	<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
						<141	<141	G1						
				2Y	3Y	<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
						<141	<141	G1						
				3Y	6Y	<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
						<141	<141	G1						
				6Y	12Y	<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
						<141	<141	G1						
				12Y	60Y	<25	<25	G4						
						<100	<100	G3						
						<125	<125	G2						
						<141	<141	G1						
		60Y	999Y	<25	<25	G4								
				<100	<100	G3								
				<125	<125	G2								
				<141	<141	G1								
		Female	0D	1D	<8.0	<80	G4							
					<9.5	<95	G3							
					<11.0	<110	G2							
				1D	8D	<12.1	<121	G1						
			<8.0			<80	G4							
			<9.5			<95	G3							
						<11.0	<110	G2						
						<12.1	<121	G1						
				8D	15D	<8.0	<80	G4						
			<9.5			<95	G3							
			<11.0			<110	G2							

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HGB

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
HGB	Continued	Male	15D	31D	<12.1	<121	G1						
					<8.0	<80	G4						
					<9.5	<95	G3						
					<11.0	<110	G2						
					<12.1	<121	G1						
					<8.0	<80	G4						
			31D	4M	<9.5	<95	G3						
					<11.0	<110	G2						
					<12.1	<121	G1						
			4M	7M	<8.0	<80	G4						
					<9.5	<95	G3						
					<11.0	<110	G2						
			7M	2Y	<12.1	<121	G1						
					<8.0	<80	G4						
					<9.5	<95	G3						
					<11.0	<110	G2						
					<12.1	<121	G1						
					<8.0	<80	G4						
			2Y	3Y	<9.5	<95	G3						
					<11.0	<110	G2						
					<12.1	<121	G1						
			3Y	6Y	<8.0	<80	G4						
					<9.5	<95	G3						
					<11.0	<110	G2						
			6Y	12Y	<12.1	<121	G1						
					<8.0	<80	G4						
					<9.5	<95	G3						
					<11.0	<110	G2						
					<12.1	<121	G1						
					<8.0	<80	G4						
			12Y	59Y	<9.5	<95	G3						
					<11.0	<110	G2						
					<12.1	<121	G1						
			59Y	999Y	<8.0	<80	G4						
					<9.5	<95	G3						
					<11.0	<110	G2						
			0D	1D	<12.1	<121	G1						
					<8.5	<85	G4						
					<10.5	<105	G3						
					<12.5	<125	G2						
					<13.6	<136	G1						
					<8.5	<85	G4						
			1D	8D	<10.5	<105	G3						
					<12.5	<125	G2						
					<13.6	<136	G1						
			8D	15D	<8.5	<85	G4						
					<10.5	<105	G3						
					<12.5	<125	G2						
		<13.6	<136	G1									
		<8.5	<85	G4									
		<10.5	<105	G3									
15D	31D	<12.5	<125	G2									
		<13.6	<136	G1									
		<8.5	<85	G4									
		<10.5	<105	G3									

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive				
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag		
HGB	Continued				<12.5	<125	G2								
					<13.6	<136	G1								
		31D	4M		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		4M	7M		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		7M	2Y		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		2Y	3Y		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		3Y	6Y		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		6Y	12Y		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		12Y	59Y		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		59Y	999Y		<8.5	<85	G4								
					<10.5	<105	G3								
					<12.5	<125	G2								
					<13.6	<136	G1								
		WBC		Female	0D	15D	<1.00	<1.00	G4						
							<1.50	<1.50	G3						
<2.50	<2.50						G2								
<3.50	<3.50						G1								
>10.79	>10.79						G1								
>15.00	>15.00						G2								
>20.00	>20.00						G3								
>25.00	>25.00						G4								
15D	31D						<1.00	<1.00	G4						
							<1.50	<1.50	G3						
							<2.50	<2.50	G2						
							<3.50	<3.50	G1						
					>10.79	>10.79	G1								
					>15.00	>15.00	G2								
					>20.00	>20.00	G3								
					>25.00	>25.00	G4								

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
WBC	Continued		31D	61D	<1.00	<1.00	G4						
					<1.50	<1.50	G3						
					<2.50	<2.50	G2						
					<3.50	<3.50	G1						
					>10.79	>10.79	G1						
					>15.00	>15.00	G2						
					>20.00	>20.00	G3						
					>25.00	>25.00	G4						
					61D	7M	<1.00	<1.00	G4				
							<1.50	<1.50	G3				
							<2.50	<2.50	G2				
							<3.50	<3.50	G1				
			>10.79	>10.79			G1						
			>15.00	>15.00			G2						
			>20.00	>20.00			G3						
			>25.00	>25.00			G4						
			7M	2Y			<1.00	<1.00	G4				
							<1.50	<1.50	G3				
							<2.50	<2.50	G2				
							<3.50	<3.50	G1				
					>10.79	>10.79	G1						
					>15.00	>15.00	G2						
					>20.00	>20.00	G3						
					>25.00	>25.00	G4						
					2Y	6Y	<1.00	<1.00	G4				
							<1.50	<1.50	G3				
							<2.50	<2.50	G2				
							<3.50	<3.50	G1				
			>10.79	>10.79			G1						
			>15.00	>15.00			G2						
			>20.00	>20.00			G3						
			>25.00	>25.00			G4						
			6Y	12Y			<1.00	<1.00	G4				
							<1.50	<1.50	G3				
							<2.50	<2.50	G2				
							<3.50	<3.50	G1				
					>10.79	>10.79	G1						
					>15.00	>15.00	G2						
					>20.00	>20.00	G3						
					>25.00	>25.00	G4						
					12Y	18Y	<1.00	<1.00	G4				
							<1.50	<1.50	G3				
							<2.50	<2.50	G2				
							<3.50	<3.50	G1				
			>10.79	>10.79			G1						
			>15.00	>15.00			G2						
			>20.00	>20.00			G3						
			>25.00	>25.00			G4						
18Y	59Y	<1.00	<1.00	G4									
		<1.50	<1.50	G3									
		<2.50	<2.50	G2									

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive						
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag				
WBC	Continued				<3.50	<3.50	G1										
					>10.79	>10.79	G1										
					>15.00	>15.00	G2										
					>20.00	>20.00	G3										
					>25.00	>25.00	G4										
					59Y	999Y	<1.00	<1.00	G4								
					<1.50	<1.50	G3										
					<2.50	<2.50	G2										
					<3.50	<3.50	G1										
					>10.79	>10.79	G1										
					>15.00	>15.00	G2										
					>20.00	>20.00	G3										
					>25.00	>25.00	G4										
					Male	0D	15D	<1.00	<1.00	G4							
					<1.50	<1.50	G3										
					<2.50	<2.50	G2										
					<3.50	<3.50	G1										
					>10.79	>10.79	G1										
					>15.00	>15.00	G2										
					>20.00	>20.00	G3										
					>25.00	>25.00	G4										
					15D	31D	<1.00	<1.00	G4								
					<1.50	<1.50	G3										
					<2.50	<2.50	G2										
		<3.50	<3.50	G1													
		>10.79	>10.79	G1													
		>15.00	>15.00	G2													
		>20.00	>20.00	G3													
		>25.00	>25.00	G4													
		31D	61D	<1.00	<1.00	G4											
		<1.50	<1.50	G3													
		<2.50	<2.50	G2													
		<3.50	<3.50	G1													
		>10.79	>10.79	G1													
		>15.00	>15.00	G2													
		>20.00	>20.00	G3													
		>25.00	>25.00	G4													
		61D	7M	<1.00	<1.00	G4											
		<1.50	<1.50	G3													
		<2.50	<2.50	G2													
		<3.50	<3.50	G1													
		>10.79	>10.79	G1													
		>15.00	>15.00	G2													
		>20.00	>20.00	G3													
		>25.00	>25.00	G4													
		7M	2Y	<1.00	<1.00	G4											
		<1.50	<1.50	G3													
		<2.50	<2.50	G2													
<3.50	<3.50	G1															
>10.79	>10.79	G1															
>15.00	>15.00	G2															

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive																		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag																
WBC	Continued					>20.00	>20.00	G3																					
						>25.00	>25.00	G4																					
					2Y	6Y	<1.00	<1.00	G4																				
							<1.50	<1.50	G3																				
							<2.50	<2.50	G2																				
							<3.50	<3.50	G1																				
							>10.79	>10.79	G1																				
							>15.00	>15.00	G2																				
							>20.00	>20.00	G3																				
							>25.00	>25.00	G4																				
							6Y	12Y	<1.00	<1.00	G4																		
									<1.50	<1.50	G3																		
									<2.50	<2.50	G2																		
									<3.50	<3.50	G1																		
									>10.79	>10.79	G1																		
									>15.00	>15.00	G2																		
									>20.00	>20.00	G3																		
									>25.00	>25.00	G4																		
								12Y	18Y	<1.00	<1.00	G4																	
										<1.50	<1.50	G3																	
										<2.50	<2.50	G2																	
										<3.50	<3.50	G1																	
										>10.79	>10.79	G1																	
										>15.00	>15.00	G2																	
										>20.00	>20.00	G3																	
										>25.00	>25.00	G4																	
								18Y	59Y	<1.00	<1.00	G4																	
										<1.50	<1.50	G3																	
										<2.50	<2.50	G2																	
										<3.50	<3.50	G1																	
										>10.79	>10.79	G1																	
										>15.00	>15.00	G2																	
										>20.00	>20.00	G3																	
										>25.00	>25.00	G4																	
								59Y	999Y	<1.00	<1.00	G4																	
										<1.50	<1.50	G3																	
										<2.50	<2.50	G2																	
										<3.50	<3.50	G1																	
										>10.79	>10.79	G1																	
										>15.00	>15.00	G2																	
										>20.00	>20.00	G3																	
										>25.00	>25.00	G4																	
					Neutrophil		Female		0D	1D	<0.50	<0.50	G4																
											<1.00	<1.00	G3																
											<1.50	<1.50	G2																
											<2.01	<2.01	G1																
											1D	8D	<0.50	<0.50	G4														
													<1.00	<1.00	G3														
		<1.50	<1.50	G2																									
		<2.01	<2.01	G1																									

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
Neutrophil	Continued	Male	8D	15D	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			15D	31D	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			31D	4M	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			4M	7M	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			7M	2Y	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			2Y	3Y	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			3Y	6Y	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			6Y	12Y	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			12Y	18Y	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			18Y	59Y	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			59Y	999Y	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
			1D	8D	<0.50	<0.50	G4						
					<1.00	<1.00	G3						
					<1.50	<1.50	G2						
					<2.01	<2.01	G1						
<0.50	<0.50	G4											
<1.00	<1.00	G3											
<1.50	<1.50	G2											
<2.01	<2.01	G1											

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive							
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag					
Neutrophil	Continued			8D	15D	<2.01	<2.01	G1										
						<0.50	<0.50	G4										
						<1.00	<1.00	G3										
				15D	31D	<1.50	<1.50	G2										
						<2.01	<2.01	G1										
						<0.50	<0.50	G4										
				31D	4M	<1.00	<1.00	G3										
						<1.50	<1.50	G2										
						<2.01	<2.01	G1										
				4M	7M	<0.50	<0.50	G4										
						<1.00	<1.00	G3										
						<1.50	<1.50	G2										
				7M	2Y	<2.01	<2.01	G1										
						<0.50	<0.50	G4										
						<1.00	<1.00	G3										
				2Y	3Y	<1.50	<1.50	G2										
						<2.01	<2.01	G1										
						<0.50	<0.50	G4										
				3Y	6Y	<1.00	<1.00	G3										
						<1.50	<1.50	G2										
						<2.01	<2.01	G1										
				6Y	12Y	<0.50	<0.50	G4										
						<1.00	<1.00	G3										
						<1.50	<1.50	G2										
				12Y	18Y	<2.01	<2.01	G1										
						<0.50	<0.50	G4										
						<1.00	<1.00	G3										
				18Y	59Y	<1.50	<1.50	G2										
						<2.01	<2.01	G1										
						<0.50	<0.50	G4										
				59Y	999Y	<1.00	<1.00	G3										
						<1.50	<1.50	G2										
						<2.01	<2.01	G1										
			Lymphocyte	Female		0D	1D	<0.25	<0.25	G4								
								<0.50	<0.50	G3								
								<0.75	<0.75	G2								
	1D	8D				<1.01	<1.01	G1										
						<0.25	<0.25	G4										

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive							
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag					
Lymphocyte	Continued	Male	0D	1D	<0.50	<0.50	G3											
					<0.75	<0.75	G2											
					<1.01	<1.01	G1											
					8D	15D	<0.25	<0.25	G4									
							<0.50	<0.50	G3									
							<0.75	<0.75	G2									
							<1.01	<1.01	G1									
						15D	31D	<0.25	<0.25	G4								
								<0.50	<0.50	G3								
								<0.75	<0.75	G2								
								<1.01	<1.01	G1								
							31D	4M	<0.25	<0.25	G4							
									<0.50	<0.50	G3							
									<0.75	<0.75	G2							
									<1.01	<1.01	G1							
								4M	7M	<0.25	<0.25	G4						
										<0.50	<0.50	G3						
										<0.75	<0.75	G2						
										<1.01	<1.01	G1						
									7M	2Y	<0.25	<0.25	G4					
											<0.50	<0.50	G3					
											<0.75	<0.75	G2					
											<1.01	<1.01	G1					
									2Y	3Y	<0.25	<0.25	G4					
											<0.50	<0.50	G3					
											<0.75	<0.75	G2					
											<1.01	<1.01	G1					
										3Y	6Y	<0.25	<0.25	G4				
												<0.50	<0.50	G3				
												<0.75	<0.75	G2				
												<1.01	<1.01	G1				
										6Y	12Y	<0.25	<0.25	G4				
												<0.50	<0.50	G3				
												<0.75	<0.75	G2				
												<1.01	<1.01	G1				
											12Y	18Y	<0.25	<0.25	G4			
													<0.50	<0.50	G3			
													<0.75	<0.75	G2			
													<1.01	<1.01	G1			
												18Y	59Y	<0.25	<0.25	G4		
														<0.50	<0.50	G3		
														<0.75	<0.75	G2		
									<1.01	<1.01	G1							
								59Y	999Y	<0.25	<0.25	G4						
										<0.50	<0.50	G3						
										<0.75	<0.75	G2						
										<1.01	<1.01	G1						
									0D	1D	<0.25	<0.25	G4					
											<0.50	<0.50	G3					
											<0.75	<0.75	G2					
											<1.01	<1.01	G1					

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
Lymphocyte	Continued		1D	8D	<0.25	<0.25	G4						
					<0.50	<0.50	G3						
					<0.75	<0.75	G2						
					<1.01	<1.01	G1						
					8D	15D	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					15D	31D	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					31D	4M	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					4M	7M	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					7M	2Y	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					2Y	3Y	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					3Y	6Y	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					6Y	12Y	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					12Y	18Y	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					18Y	59Y	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
					59Y	999Y	<0.25	<0.25	G4				
							<0.50	<0.50	G3				
							<0.75	<0.75	G2				
							<1.01	<1.01	G1				
Total Bili		Both	0D	14D	>12.8	>219	SF						
					>14.6	>250	SF						

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive				
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag		
Total Bili	Continued				>17.6	>301	SF								
					>20.5	>351	SF								
		14D	18Y		>1.2	>21	SF								
					>1.5	>26	SF								
					>1.8	>31	SF								
					>2.1	>36	SF								
		18Y	999Y		>1.2	>21	SF								
					>1.5	>26	SF								
					>1.8	>31	SF								
					>2.1	>36	SF								
		ALT (SGPT)		Female	0Y	1Y	>58	>58	G1						
							>135	>135	G2						
							>270	>270	G3						
							>540	>540	G4						
1Y	4Y				>36	>36	G1								
					>85	>85	G2								
					>170	>170	G3								
					>340	>340	G4								
4Y	7Y				>36	>36	G1								
					>85	>85	G2								
					>170	>170	G3								
					>340	>340	G4								
7Y	10Y				>36	>36	G1								
					>85	>85	G2								
				>170	>170	G3									
				>340	>340	G4									
10Y	18Y			>36	>36	G1									
				>85	>85	G2									
				>170	>170	G3									
				>340	>340	G4									
Male				0Y	1Y	>46	>46	G1							
						>108	>108	G2							
						>215	>215	G3							
						>430	>430	G4							
						>58	>58	G1							
						>135	>135	G2							
						>270	>270	G3							
				1Y	4Y	>540	>540	G4							
		>36	>36			G1									
		>85	>85			G2									
		4Y	7Y	>170	>170	G3									
				>340	>340	G4									
				>36	>36	G1									
		7Y	10Y	>85	>85	G2									
>170	>170			G3											
>340	>340			G4											

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
ALT (SGPT)	Continued		10Y	18Y	>46	>46	G1						
					>108	>108	G2						
					>215	>215	G3						
					>430	>430	G4						
			18Y	999Y	>52	>52	G1						
					>120	>120	G2						
					>240	>240	G3						
					>480	>480	G4						
					Female	0M	1M	>1.49	>132	G1			
								>1.70	>150	G2			
								>2.00	>177	G3			
								>2.50	>221	G4			
1M	1Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
1Y	4Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
4Y	7Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
7Y	10Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
10Y	13Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
13Y	16Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
16Y	18Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
18Y	50Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
50Y	70Y	>1.49	>132	G1									
		>1.70	>150	G2									
		>2.00	>177	G3									
		>2.50	>221	G4									
70Y	80Y	>1.49	>132	G1									
		>1.70	>150	G2									

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive				
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag		
Creatinine	Continued	Male			>2.00	>177	G3								
					>2.50	>221	G4								
					80Y 999Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					0M 1M	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					1M 1Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					1Y 4Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					4Y 7Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					7Y 10Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					10Y 13Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					13Y 16Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					16Y 18Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					18Y 50Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					50Y 70Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					70Y 80Y	>1.49	>132	G1							
					>1.70	>150	G2								
					>2.00	>177	G3								
					>2.50	>221	G4								
					80Y 999Y	>1.49	>132	G1							

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive						
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag				
Creatinine	Continued				>1.70	>150	G2										
					>2.00	>177	G3										
					>2.50	>221	G4										
Alk Phos		Female	0D	15D	>272	>272	G1										
					>496	>496	G2										
					>744	>744	G3										
					>2480	>2480	G4										
					15D	1Y	>515	>515	G1								
							>938	>938	G2								
							>1407	>1407	G3								
							>4690	>4690	G4								
					1Y	10Y	>368	>368	G1								
							>670	>670	G2								
							>1005	>1005	G3								
							>3350	>3350	G4								
					10Y	13Y	>458	>458	G1								
							>834	>834	G2								
							>1251	>1251	G3								
							>4170	>4170	G4								
					13Y	15Y	>278	>278	G1								
							>508	>508	G2								
							>762	>762	G3								
							>2540	>2540	G4								
					15Y	17Y	>128	>128	G1								
							>234	>234	G2								
							>351	>351	G3								
							>1170	>1170	G4								
					17Y	19Y	>95	>95	G1								
							>174	>174	G2								
							>261	>261	G3								
							>870	>870	G4								
					19Y	999Y	>113	>113	G1								
							>208	>208	G2								
							>312	>312	G3								
							>1040	>1040	G4								
					Male		0D	15D	>272	>272	G1						
									>496	>496	G2						
									>744	>744	G3						
									>2480	>2480	G4						
									15D	1Y	>515	>515	G1				
											>938	>938	G2				
											>1407	>1407	G3				
											>4690	>4690	G4				
									1Y	10Y	>368	>368	G1				
											>670	>670	G2				
											>1005	>1005	G3				
											>3350	>3350	G4				
									10Y	13Y	>458	>458	G1				
											>834	>834	G2				
>1251	>1251	G3															

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive										
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag								
Alk Phos	Continued					>4170	>4170	G4													
						13Y	15Y	>514	>514	G1											
								>936	>936	G2											
								>1404	>1404	G3											
								>4680	>4680	G4											
						15Y	17Y	>363	>363	G1											
								>662	>662	G2											
								>993	>993	G3											
								>3310	>3310	G4											
						17Y	19Y	>163	>163	G1											
								>298	>298	G2											
								>447	>447	G3											
								>1490	>1490	G4											
						19Y	999Y	>141	>141	G1											
								>258	>258	G2											
								>387	>387	G3											
								>1290	>1290	G4											
						AST (SGOT)		Female				0Y	1Y	>87	>87	G1					
														>200	>200	G2					
														>400	>400	G3					
		>800	>800	G4																	
1Y	4Y	>61	>61	G1																	
		>140	>140	G2																	
		>280	>280	G3																	
		>560	>560	G4																	
4Y	7Y	>52	>52	G1																	
		>120	>120	G2																	
		>240	>240	G3																	
		>480	>480	G4																	
7Y	18Y	>43	>43	G1																	
		>100	>100	G2																	
		>200	>200	G3																	
		>400	>400	G4																	
18Y	999Y	>43	>43	G1																	
		>100	>100	G2																	
		>200	>200	G3																	
		>400	>400	G4																	
Male	0Y	1Y	>87	>87	G1																
		>200	>200	G2																	
		>400	>400	G3																	
		>800	>800	G4																	
1Y	4Y	>75	>75	G1																	
		>173	>173	G2																	
		>345	>345	G3																	
		>690	>690	G4																	
4Y	7Y	>64	>64	G1																	
		>148	>148	G2																	
		>295	>295	G3																	
		>590	>590	G4																	
7Y	18Y	>43	>43	G1																	

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Test	Race	Sex	Ages		Parameter Reach Value			Negative			Positive		
			Low	High	Conventional	SI	Flag	Conv	SI	Flag	Conv	SI	Flag
AST (SGOT)	Continued				>100	>100	G2						
					>200	>200	G3						
					>400	>400	G4						
		18Y	999Y		>43	>43	G1						
					>100	>100	G2						
					>200	>200	G3						
					>400	>400	G4						
Urea Nitr		Both	0Y	18Y	>22	>8.0	G1						
					>26	>9.4	G2						
					>31	>11.2	G3						
			18Y	70Y	>22	>8.0	G1						
					>26	>9.4	G2						
					>31	>11.2	G3						
			70Y	80Y	>22	>8.0	G1						
					>26	>9.4	G2						
					>31	>11.2	G3						
			80Y	999Y	>22	>8.0	G1						
					>26	>9.4	G2						
					>31	>11.2	G3						

- Flags:
- G1 Toxicity Grade 1
 - G2 Toxicity Grade 2
 - G3 Toxicity Grade 3
 - G4 Toxicity Grade 4
 - H1 Sponsor Flag
 - HY Hy's Law
 - SF Sponsor Flag

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16.1.10 List of Laboratories

List of Laboratories – Final Analysis Interim

Organization	Address	Service(s) Provided
Pfizer Vaccine Research & Development	401 N Middletown Road Pearl River, NY 10965 USA	S1-binding IgG level assay; RBD-binding IgG level assay; N-binding antibody assay; and RT-PCR on nasal swabs for SARS-CoV-2.
Pfizer Vaccine Research & Development ^a	111 Ideation Way Nutley, NJ 07110 USA	SARS-CoV-2 neutralization assay - NT50 and NT90.
University of Texas Medical Branch ^b	Department of Biochemistry & Molecular Biology University of Texas Medical Branch (b) (4), (b) (6) Galveston, TX 77555-1055 USA	SARS-CoV-2 neutralization assay - NT50 and NT90.
Covance Central Laboratory Services	8211 SciCor Drive Indianapolis, IN 46214 USA	<u>Phase 1 Safety Labs:</u> hematology panel (hemoglobin, complete blood count with differential, and platelets); blood chemistry (ALT, AST, alkaline phosphatase, total bilirubin, BUN, and creatinine). <u>Phase 1 Screening Labs:</u> HIV, HBsAg, HBc Ab, and HCV Ab.

Abbreviations: ALT = alanine aminotransferase; AST = aspartate aminotransferase; BUN = blood urea nitrogen; HBc Ab = hepatitis B core antibody; HBsAg = hepatitis B surface antigen; HCV Ab = hepatitis C virus antibody; HIV = human immunodeficiency virus; IgG = immunoglobulin G; N = SARS-CoV-2 nucleoprotein; NT50 = 50% neutralizing titer; NT90 = 90% neutralizing titer; RBD = receptor-binding domain; RT-PCR = reverse transcription–polymerase chain reaction; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

- a. Pfizer Vaccine Research & Development, Nutley, NJ, performed the neutralization assays for Phase 2/3.
- b. The University of Texas Medical Branch, Galveston, TX, performed the neutralization assays for Phase 1.

Protocol C4591001 List of Laboratories – Final Analysis Interim, Final, Version 1.0, 20Nov2020.

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