

# Laboratory Data Elements

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Children's Health

UT Southwestern Medical Center

# Clinical Interoperability

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     ▾ TOXICOLOGY  
   ▾ RADIOLOGY/IMAGING  
     ▾ GENERAL DIAGNOSTIC  
   ... OTHERS

	1	2	3	4	5
	11/19/2021 1809	8/24/2021 0217	8/23/2021 0000	7/7/2021 0335	12/3/2019 0000
<b>VIRAL TESTS</b>					
COVID-19 - 2019 No...				<i>Not Detected</i> ▼	
RESPIRATORY PANEL ...	📄				
OSH-RSV Screen			<i>Negative</i>		<i>Negative</i>
Influenza A		<i>Negative *</i>			
Influenza B		<i>Negative *</i>			
RSV		<i>Negative *</i>			
SARS-CoV-2		<i>Negative *</i>			

# Clinical Interoperability

✓ This outside test result is acceptable at Children's as an equivalent screening/diagnostic test.

## COVID-19 - 2019 NOVEL CORONAVIRUS SENDOUT

Order: 169898369

Status: Final result

Component	7 mo ago
<b>Specimen Source</b>	<b>Nasopharynx</b>
COVID-19 - 2019 Novel Coronavirus	Not detected
2019-nCoV Comment	A negative result does not preclude infection by any respiratory virus or other agent.
Comment:	
	This assay has been granted FDA Emergency Use Authorization and has been validated by the Henry Ford Department of Pathology.
	<b>Tests performed by the Cobas Liat System, an automated multiplex real-time RT-PCR assay.</b>
	Test performed at Henry Ford W. Bloomfield Hospital Laboratory, 6777 W. Maple Rd, W. Bloomfield, MI 48322. Ph. 313.916.5227
	CLIA Certificate No. 23D0036815, ISO 15189 accredited.
	Jason Pimental, MD, Medical Director
Is patient pregnant?	No.
First Test for COVID-19?	No.
Employed in a Healthcare setting?	No.
Is Patient Symptomatic?	No.
If yes, Date of Symptom Onset:	NOT APPLICABLE
Hospitalized for COVID-19?	No.
ICU Patient for COVID-19?	No.
Resident in a congregate care setting?	No.
Resulting Agency	<a href="#">HENRY FORD WEST BLOOMFIELD LABORATORY</a>


Specimen Collected: 05/30/21 18:23  
Received From: Henry Ford Health System


Last Resulted: 05/30/21 19:19  
Result Received: 07/30/21 11:34



[Lab Flowsheet](#) [Order Details](#) [View Encounter](#) [Lab and Collection Details](#) [Received Information](#) [Result History](#)

# Clinical Interoperability

 This outside test result is not acceptable at Children's as an equivalent screening/diagnostic test.

 Information displayed in this report will not trend and will not trigger automated decision support.

COVID/FLU/RSV (Clinic Only)		6 mo ago	Order: 166343364
SARS-COV-2	Ref Range & Units Negative	Negative	
Influenza A	Negative	Negative	
Influenza B	Negative	Negative	
RSV	Negative	Negative	
Resulting Agency		CRMOB CHILDREN'S CLINIC	
Specimen Collected: 07/08/21 09:27		Last Resulted: 07/08/21 10:29	
Received From: Cheyenne Regional Medical Center 		Result Received: 08/17/21 07:43	

 [View Encounter](#)  [Received Information](#)

# Device and Test Kit Differences

## D-dimer Quantitative

UOM/REAGENT/RESULT	CG-DD1							CG-DD2						
	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH
<b>mg/L or µg/mL DDU</b>														
DIAG STAGO LIATEST	104	1.497	0.071	4.7	1.50	1.34	1.70	100	0.347	0.053	15.1	0.34	0.24	0.51
SIEMENS INNOVANCE	67	2.139	0.137	6.4	2.13	1.81	2.50	64	0.370	0.041	11.1	0.36	0.29	0.48
<b>ng/mL or µg/L DDU</b>														
DIAG STAGO LIATEST	28	742.745	40.010	5.4	742.95	646.97	842.00	20	165.491	22.210	13.4	161.77	135.00	214.14
HEMOSIL (ACL 7/8/9/10K,ELITE)	65	548.538	41.222	7.5	542.00	435.00	640.00	60	228.660	33.836	14.8	224.00	144.00	296.00
HEMOSIL (ACL FUT/ADV, TOP)	117	711.890	33.011	4.6	712.00	638.00	804.00	66	214.273	14.882	6.9	212.00	173.00	238.00
HEMOSIL D-DIMER HS	334	680.447	38.708	5.7	678.50	565.00	796.00	245	168.330	21.542	12.8	164.95	104.00	245.00
HEMOSIL D-DIMER HS 500	21	674.190	42.064	6.2	663.00	598.00	775.00	16	168.813	20.150	11.9	161.00	144.00	219.00
QUIDEL TRIAGE	80	1731.750	166.199	9.6	1720.00	1340.00	2090.00	73	171.945	26.161	15.2	172.00	113.00	236.00
<b>mg/L or µg/mL FEU</b>														
DIAG STAGO LIATEST	1269	1.494	0.079	5.3	1.49	1.05	2.04	1193	0.350	0.052	14.9	0.35	0.20	0.59
HEMOSIL D-DIMER HS 500	101	1.944	0.099	5.1	1.94	1.69	2.22	101	0.418	0.040	9.5	0.41	0.32	0.54
LSI MEDINC PATHEFAST	-	-	-	-	-	-	-	10	0.713	0.056	7.9	0.73	0.62	0.80
ROCHE COBAS c SERIES	28	0.771	0.102	13.2	0.76	0.60	0.97	28	0.290	0.054	18.5	0.28	0.20	0.41
SIEMENS INNOVANCE	780	2.109	0.135	6.4	2.10	1.64	2.62	771	0.363	0.039	10.6	0.36	0.28	0.49
<b>ng/mL or µg/L FEU</b>														
BIOMERIEUX VIDAS/3/MINI	76	1790.688	107.714	6.0	1793.45	1591.20	2082.00	76	350.363	23.534	6.7	348.50	301.84	413.00
DIAG STAGO LIATEST	84	1486.417	66.350	4.5	1487.87	1320.00	1640.00	76	347.723	58.571	16.8	330.00	200.00	530.00
HEMOSIL (ACL 7/8/9/10K,ELITE)	16	1139.843	169.104	14.8	1095.50	1002.00	1715.00	20	439.567	61.216	13.9	453.37	287.00	527.00
HEMOSIL D-DIMER HS 500	533	1955.603	113.904	5.8	1952.70	1603.00	2337.00	532	427.521	48.968	11.5	428.00	260.00	594.00
SIEMENS INNOVANCE	81	2091.358	106.005	5.1	2091.50	1845.00	2400.00	80	358.788	33.580	9.4	350.00	290.00	460.00
SIEMENS STRATUS CS	17	1524.235	70.950	4.7	1524.00	1408.00	1709.00	18	363.444	18.834	5.2	360.00	335.00	399.00

LOINC CODE  
**48067-3**

LONG COMMON NAME  
**Fibrin D-dimer FEU [Mass/volume] in Platelet poor plasma by Immunoassay**

LOINC STATUS  
**Active**

**D-dimer Quantitative**

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	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH
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# Clinical Comparability

<b>COAG OTHER</b>							
D-Dimer, Quant							<i>0.38 *</i>
Fibrinogen							<i>221</i>
<b>HEPARIN STUDIES</b>							
Heparin Unfraction...	<i>0.55 *</i>	<i>0.46 *</i>	<i>0.34 *</i>	<i>0.30 *</i>	<i>0.17 *</i>		
Heparin Type	<i>Porcine *</i>	<i>Porcine *</i>	<i>Porcine *</i>	<i>Porcine *</i>	<i>Porcine *</i>		
<b>HYPERCOAGULATION</b>							
Prothrombin Mutation							<i>Normal</i>
Prothrombin Gene M...							<i>Factor II Norm... *</i>
Factor V Leiden							<i>Normal</i>
Factor V Leiden In...							<i>Factor V Norma... *</i>
<b>PROTIME W/ INR</b>							
Protime	<i>13.5 *</i>			<i>14.9 *</i>			<i>12.9 *</i>
INR	<i>1.0 *</i>			<i>1.1 *</i>			<i>0.9 *</i>
<b>PTT</b>							
PTT	<i>86.0 ▲</i>			<i>61.9 *</i> ▲			<i>27.1</i>

# Clinical Comparability

## Chart Review



Encounters

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**Labs**

Pathology

Imaging

Procedures

C

Lab Reports



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Flowsheet



Search:

New results (No timemark set)

ALL TOPICS

Results

LABORATORY RESULTS

BLOOD

COAGULATION

COAG OTHER

D-Dimer, Quant

OTHERS

### COAG OTHER

D-Dimer, Quant

2

6/1/2021  
1122

1

6/1/2021  
1123

*0.38*

*4.30*





# Device and test kit differences

Method	Number	Coefficient of Variation (%)
1	159	26.2
2	25	35
3	13	9.8
4	164	26.8
5	145	40.7
6	168	30.6
7	45	34.9
8	16	29.8
9	16	17.3

Mean Result Ranges: 1556 to 4371 nG/mL CG2-A;2004

# CLINICAL INTEROPERABILITY

- Clinical interoperability is the ability of two or more systems to exchange information (laboratory results) and to use equivalent results for trending purposes, clinical decision support and machine learning algorithms.
- Lab data will only achieve true, safe clinical interoperability if one of the two conditions are met:
  - Same test (defined as same analyte/observable performed on the same specimen type)
  - Same Instrument Platform
  - Same Test Kit
- OR
- Same Test
- The IVD manufacturer has calibrated their assay to a reference “gold standard” in order to harmonize their results with those of other IVD manufacturers. Only assays that undergone this harmonization process can be considered equivalent regardless of platform and/or test kit.