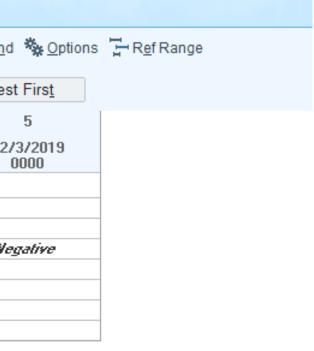
# Laboratory Data Elements

Hung S. Luu, PharmD, MD Children's Health **UT Southwestern Medical Center** 

# Clinical Interoperability

Chart Review Results Review	W SnapShot						
Results Review ← Back → Forward \\	v → 🕒 Hide Tree 🛛 Load <u>A</u> ll 🏢 Flo	wsheet 🖄 <u>G</u> raph	🕹 Time Mar <u>k</u>	CLast Refresh:	1/17/2022 1552	Lege <u>n</u> a	d
Search:	New results (No tin	nemark set)			Newest Fir <u>s</u> t	Oldes	st
ALL TOPICS È- Results È- LABORATORY RESULTS		1 11/19/2021	2 8/24/2021	3 8/23/2021	4 7/7/2021	12	
B-BLOOD B-INFECTIOUS DISEASE	VIRAL TESTS	1809	0217	0000	0335		0
ia TOXICOLOGY ⊨- RADIOLOGY/ IMAGING	COVID-19 - 2019 No RESPIRATORY PANEL	*@			Not Detected	\ 	_
■ GENERAL DIAGNOSTIC OTHERS	OSH-RSV Screen Influenza A		Negative *	Negative		No	ey
	Influenza B RSV		Negative * Negative *				
	SARS-CoV-2		Negative *				



# Clinical Interoperability

## Henry Ford Health System

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

### COVID-19 - 2019 NOVEL CORONAVIRUS SENDOUT

Status: Final result

Component	7 mo ago
Specimen Source	Nasopharynx
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:	
	gency Use Authorization and has been validated by the Henry Ford Department of Pathology.
Tests performed by the Cobas Liat S	ystem, an automated multiplex real-time RT-PCR assay.
Test performed at Henry Ford M Pla	mfield Hospital Laboratory, 6777 W. Maple Rd, W. Bloomfield, MI 48322. Ph. 313.916.5227
CLIA Certificate No. 23D0036815, IS	
Jason Pimental, MD, Medical Directo	
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	HENRY FORD WEST BLOOMFIELD LABORATORY
pecimen Collected: 05/30/21 18:23	Last Resulted: 05/30/21 19:19
eceived From: Henry Ford Health System 🕑	Result Received: 07/30/21 19:19
ceived From. Henry Ford Health System 🦿	Result Received. 07/50/21 11.54
	I ab Flowsheet 🧔 Order Details 😗 View Encounter 🔰 Lab and Collection

**Outside Information** Order: 169898369 etails Received Information 🤊 Result History

# Clinical Interoperability

### Cheyenne Regional Medical Center

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

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

### L COVID/FLU/RSV (Clinic Only)

SARS-COV-2	Ref Range & Units Negative	6 mo ago
	2	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

**Outside Information** 

Order: 166343364

N View Encounter € Received Information

4

## Device and Test Kit Differences

## **D-dimer Quantitative**

	CG-DD1						CG-DD2							
UOM/REAGENT/RESULT	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH	LABS	MEAN	SD	CV I	MEDIAN	LOW	HIGH
mg/L or μg/mL DDU														
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
ng/mL or μg/L DDU														
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 <mark>50</mark>	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. <mark>00</mark>	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
mg/L or μg/mL FEU														
DIAG STAGO LIATEST	1269	1.494	0.079	5.3	1. <mark>4</mark> 9	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	1/74	1.69	2.22	101	0.418	0.040	9.5	0.41	0.32	0.54
LSI MEDINC PATHEAST	-	-	_	-	_	-	-	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
ng/mL or µg/L FEU														
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

## Fibrin D-dimer FEU [Mass/volume] in Platelet poor plasma by Immunoassay

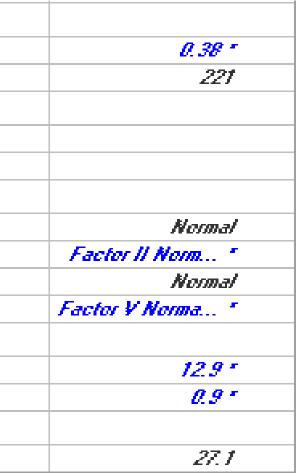
## **D-dimer Quantitative**

	CG-DD1						CG-DD2							
UOM/REAGENT/RESULT	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH
mg/L or μg/mL FEU														
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 PATHFAST	-	-	-	-	-	-	-	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
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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
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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

## Active

# Clinical Comparability

COAG OTHER						
D-Dimer, Quant						
Fibrinogen						
HEPARIN STUDIES						
Heparin Unfraction	0.55 *	0.46 *	0.34 *	0.30 *	0.17 *	
Heparin Type	Porcine *					
HYPERCOAGULATION						
Prothrombin Mutation						
Prothrombin Gene M						
Factor V Leiden						
Factor V Leiden In						
PROTIME W/ INR						
Protime	13.5 *			14.9 *		
INB	1.0 *			1.1 *		
PTT						
PTT	BE. 0 🔶			61.9 * 🔶		



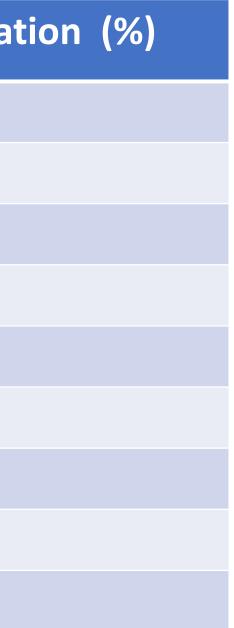
# Clinical Comparability



## Device and test kit differences

Method	Number	<b>Coefficient of Varia</b>
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.