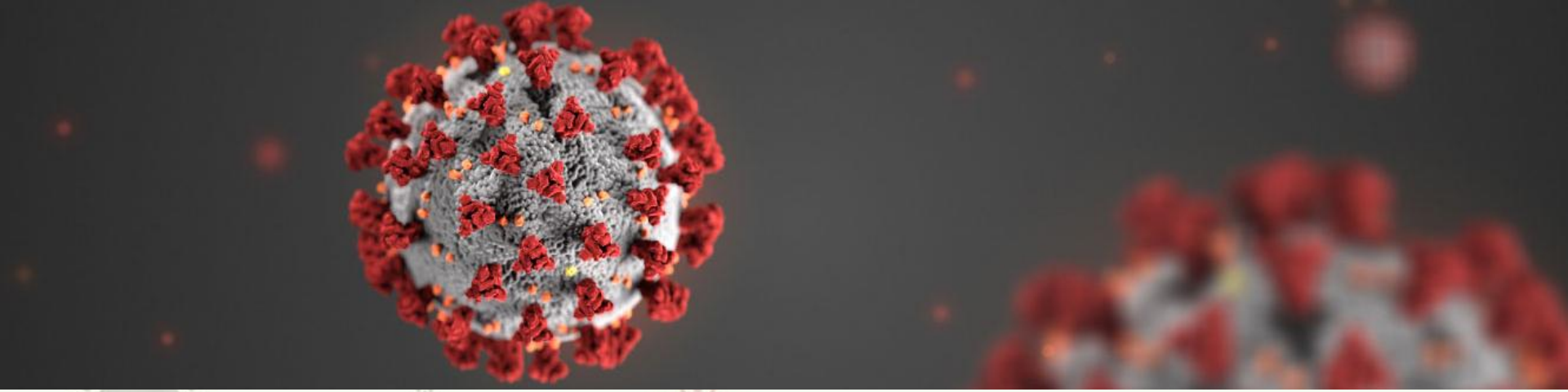
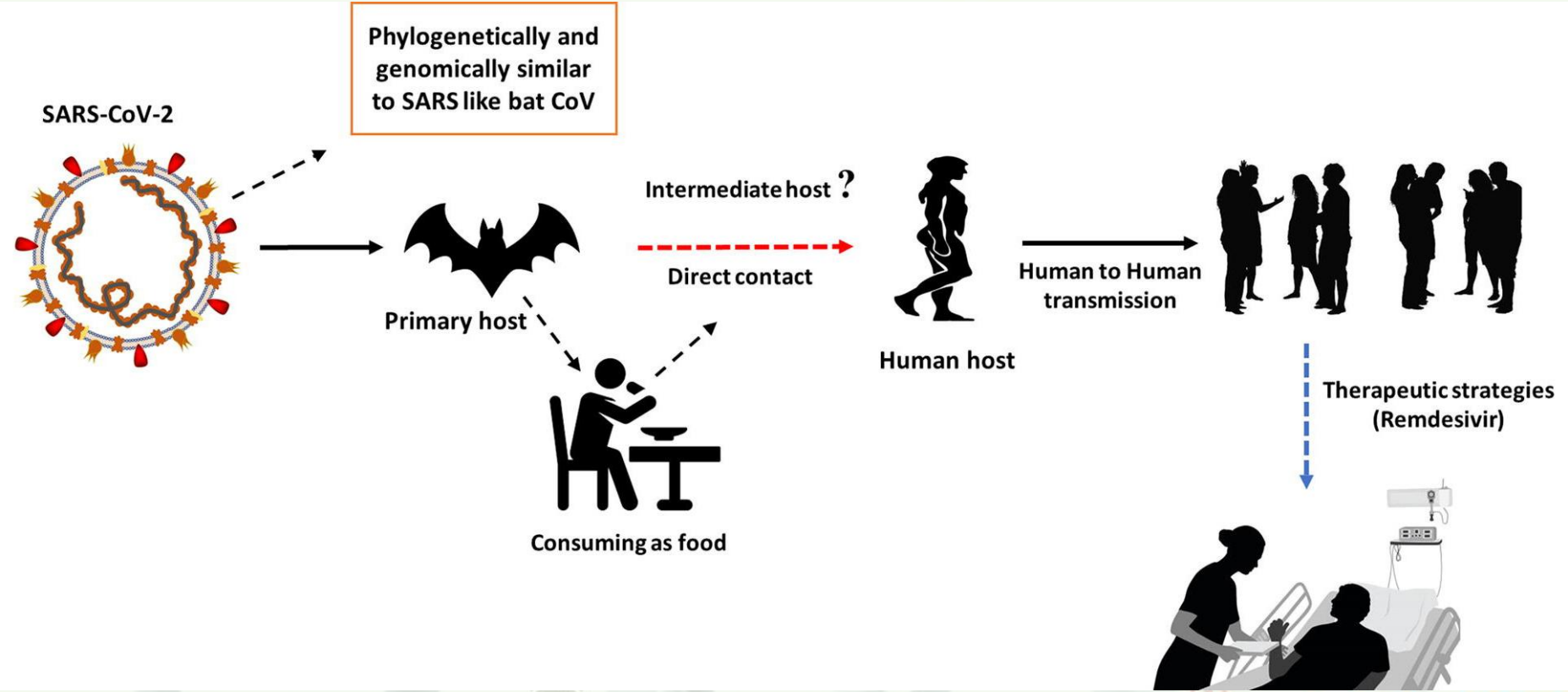


Setting up a Coronavirus (COVID-19) Clinical Diagnostic Testing Lab? LIMS for Automation and Data Management

Shonali Paul
Chief Operating Officer, CloudLIMS.com

CloudLIMS
Empowering Labs

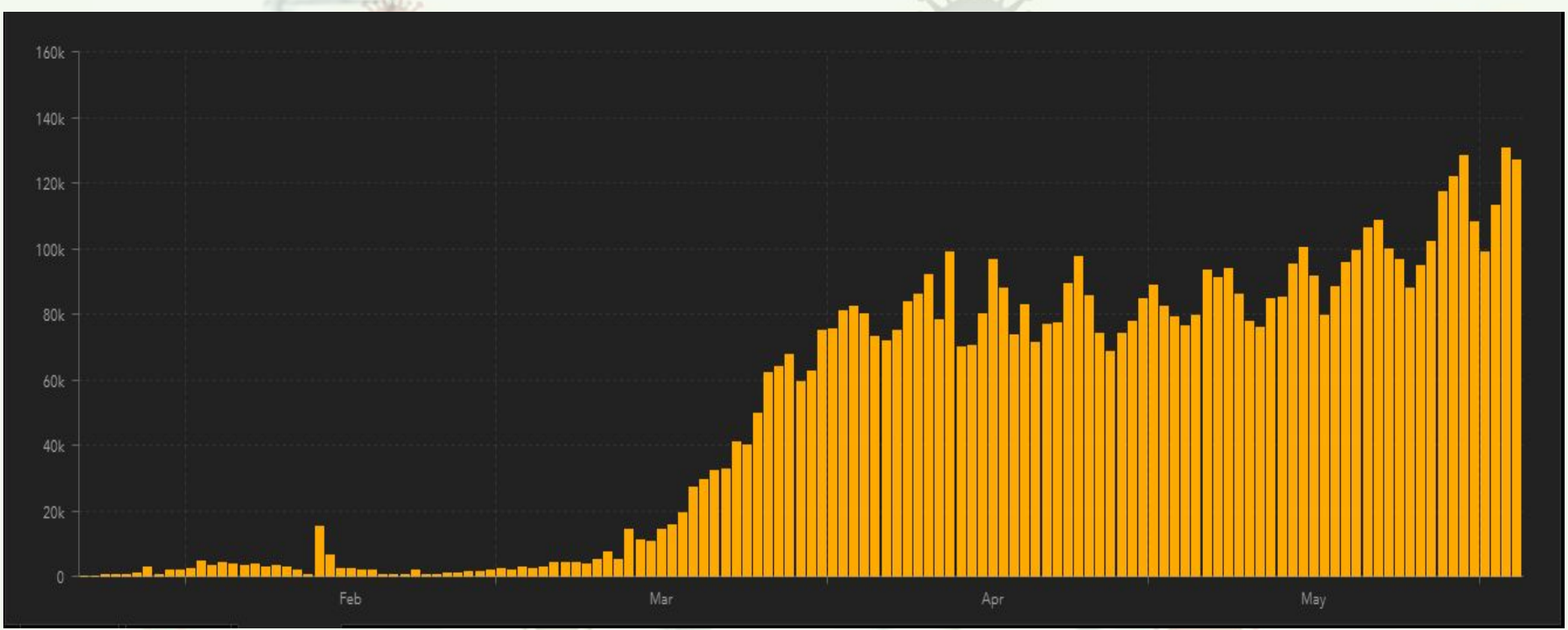
COVID-19 (SARS-CoV-2): The Origin



Source: Sciencedirect

CloudLIMS
Empowering Labs

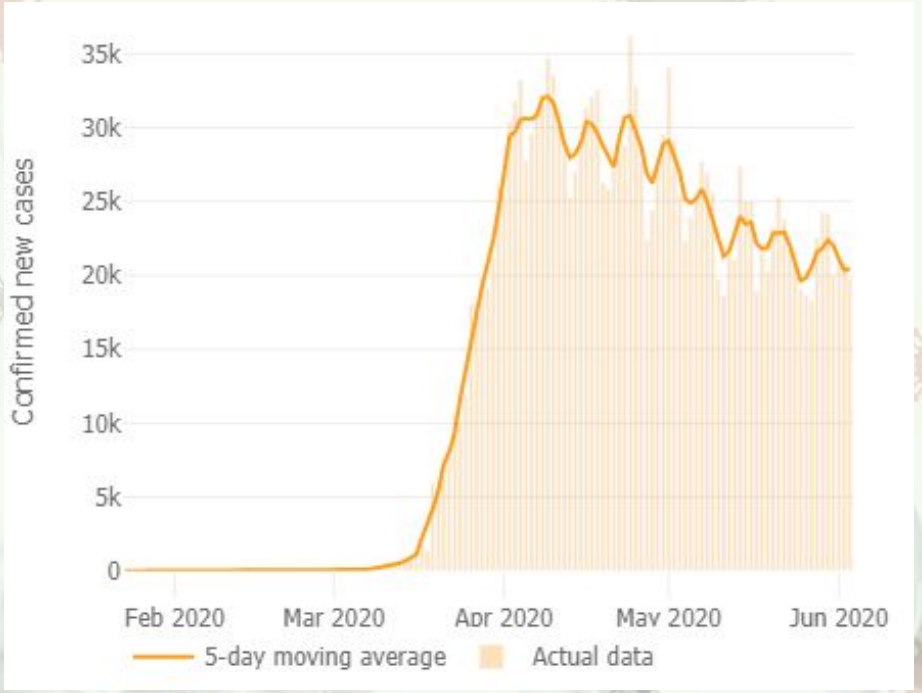
COVID-19 (SARS-CoV-2): The Pandemic



Source: https://coronavirus.jhu.edu/map.html

CloudLIMS
Empowering Labs

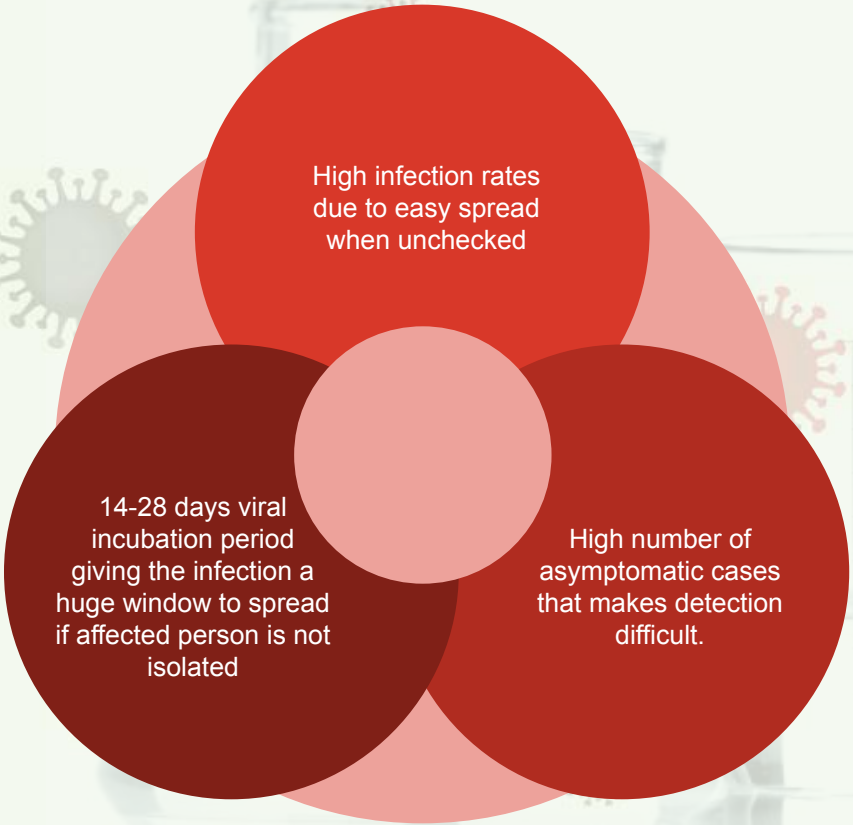
COVID-19 (SARS-CoV-2): The Pandemic



Source: https://coronavirus.jhu.edu/data/new-cases

CloudLIMS
Empowering Labs

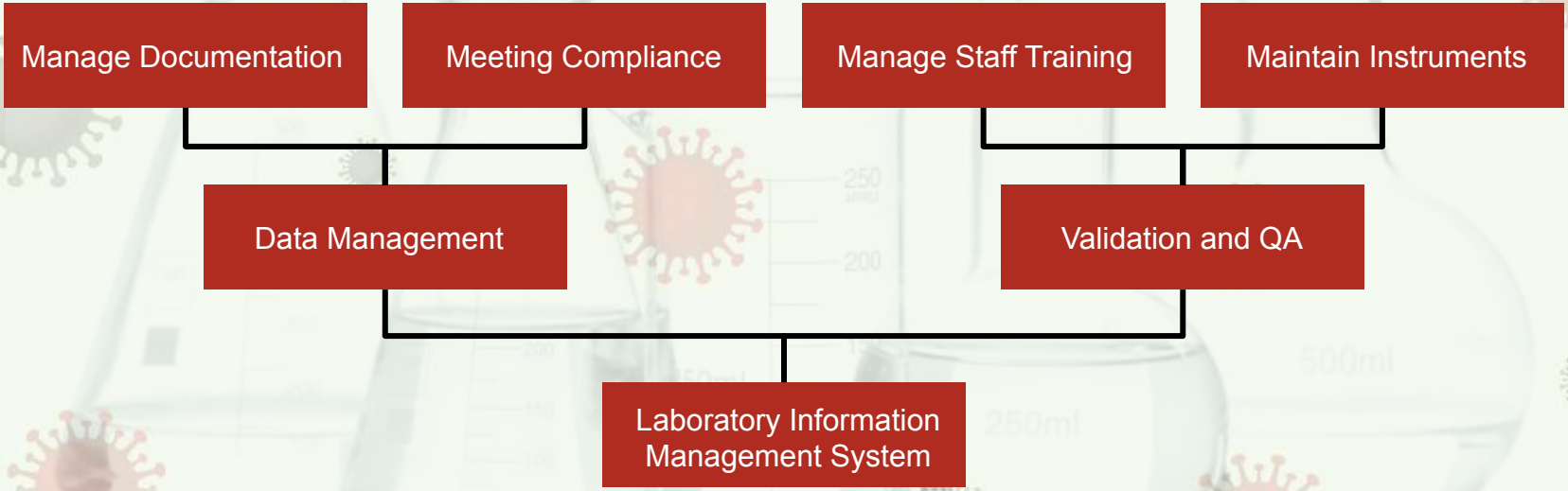
Testing, Testing & Testing



Need for rapid testing

CloudLIMS
Empowering Labs

Rapid Testing Challenges



CloudLIMS
Empowering Labs

Lab Automation

Role of LIMS in Lab Automation

CloudLIMS
Empowering Labs

COVID-19 Diagnostic Lab Workflow

Physician Registration

Sample Accessioning Through Client Portal

Sample Test Request Through Client Portal

Storing Samples

Patient Registration & Sample Association

Conducting Tests

Recording Test Results

Validating Test Results

Generating Test Reports

Emailing Reports and Invoices

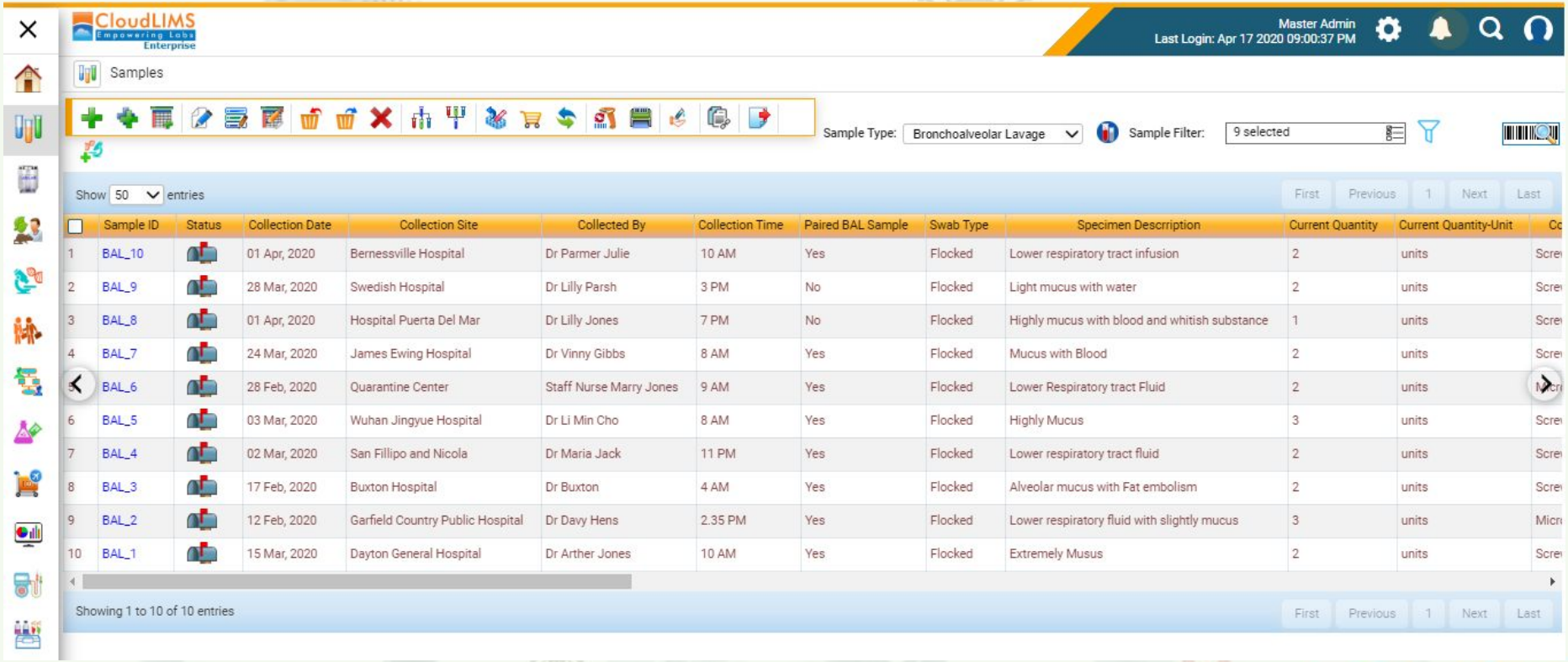
Disposing Samples

CloudLIMS
Empowering Labs

How Does a LIMS Help?

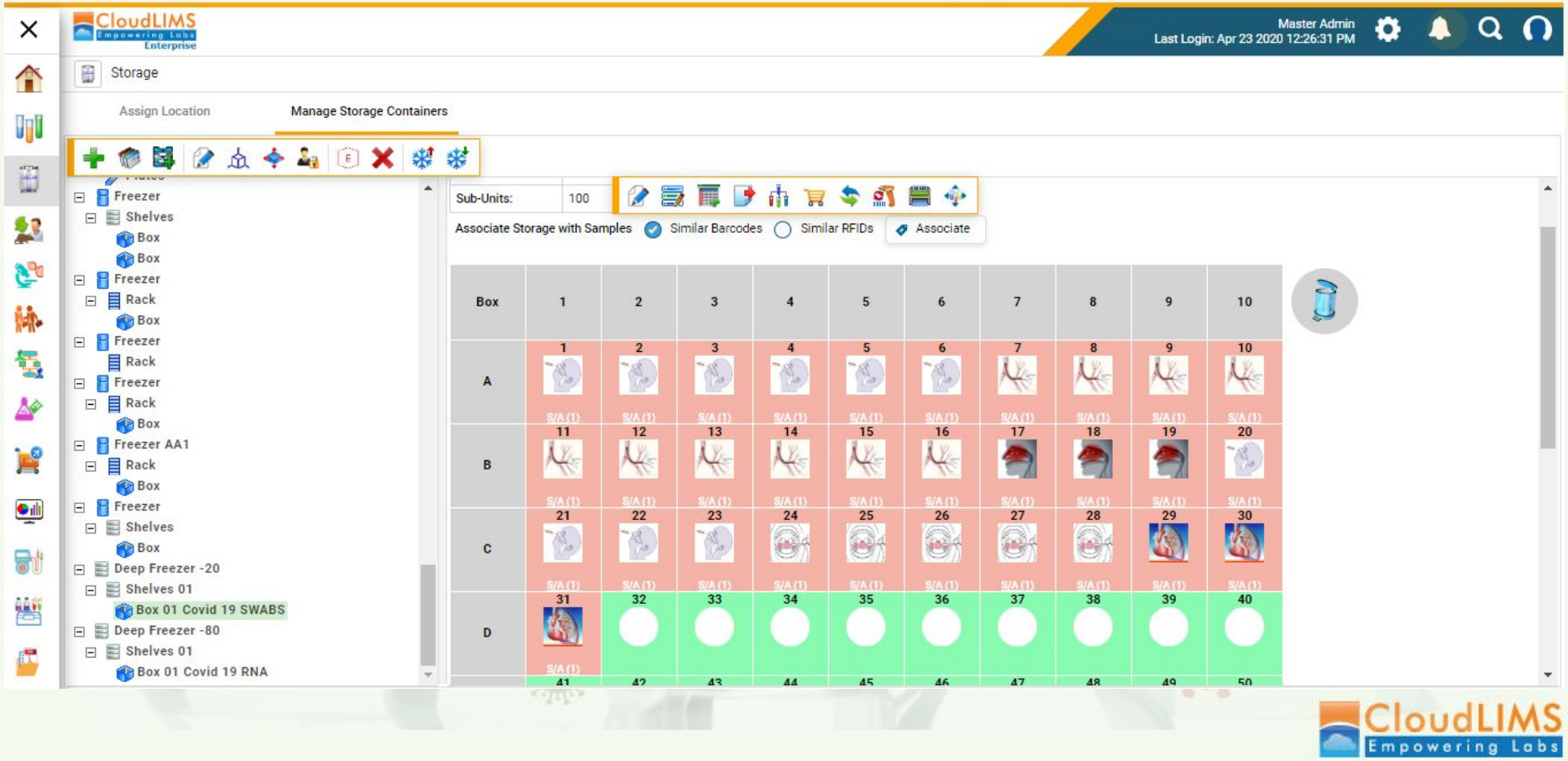
CloudLIMS
Empowering Labs

Managing Samples



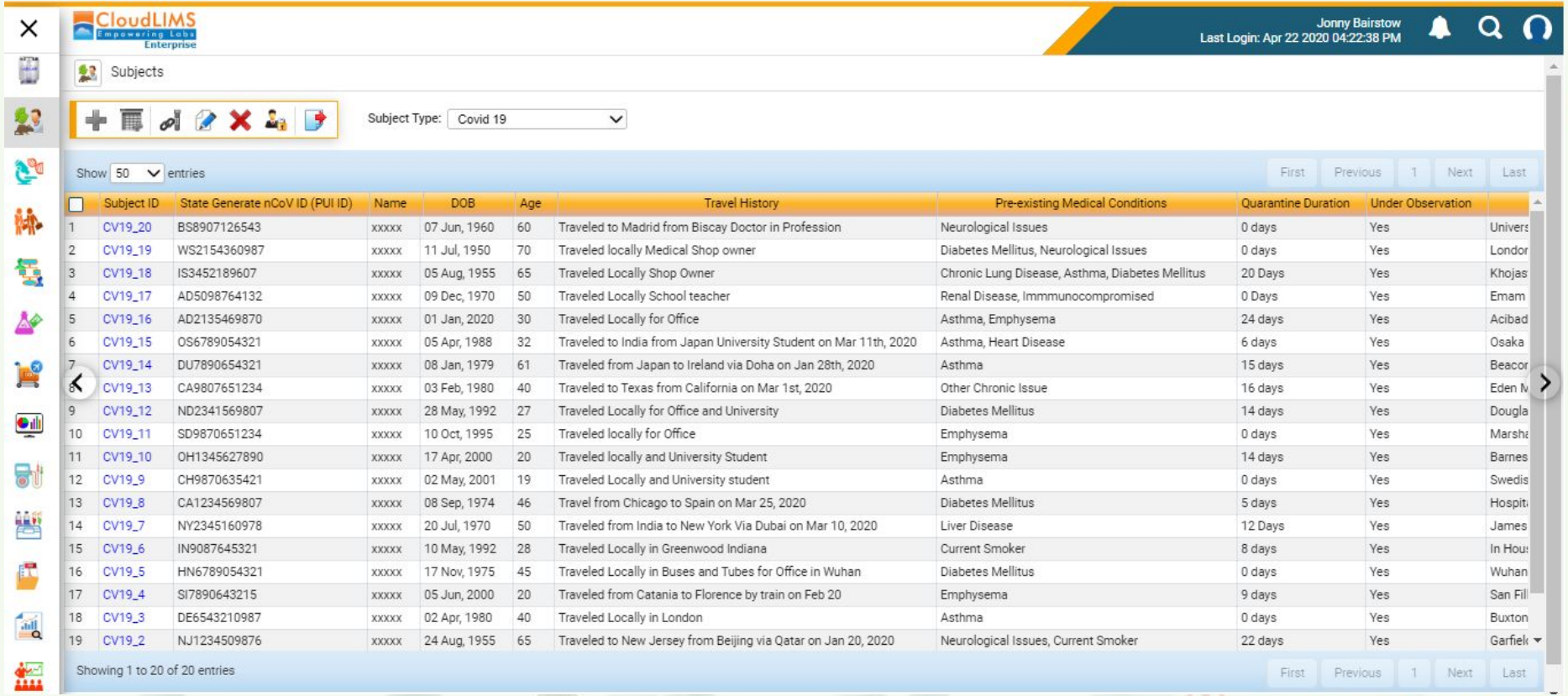
CloudLIMS
Empowering Labs

Tracking Samples



CloudLIMS
Empowering Labs

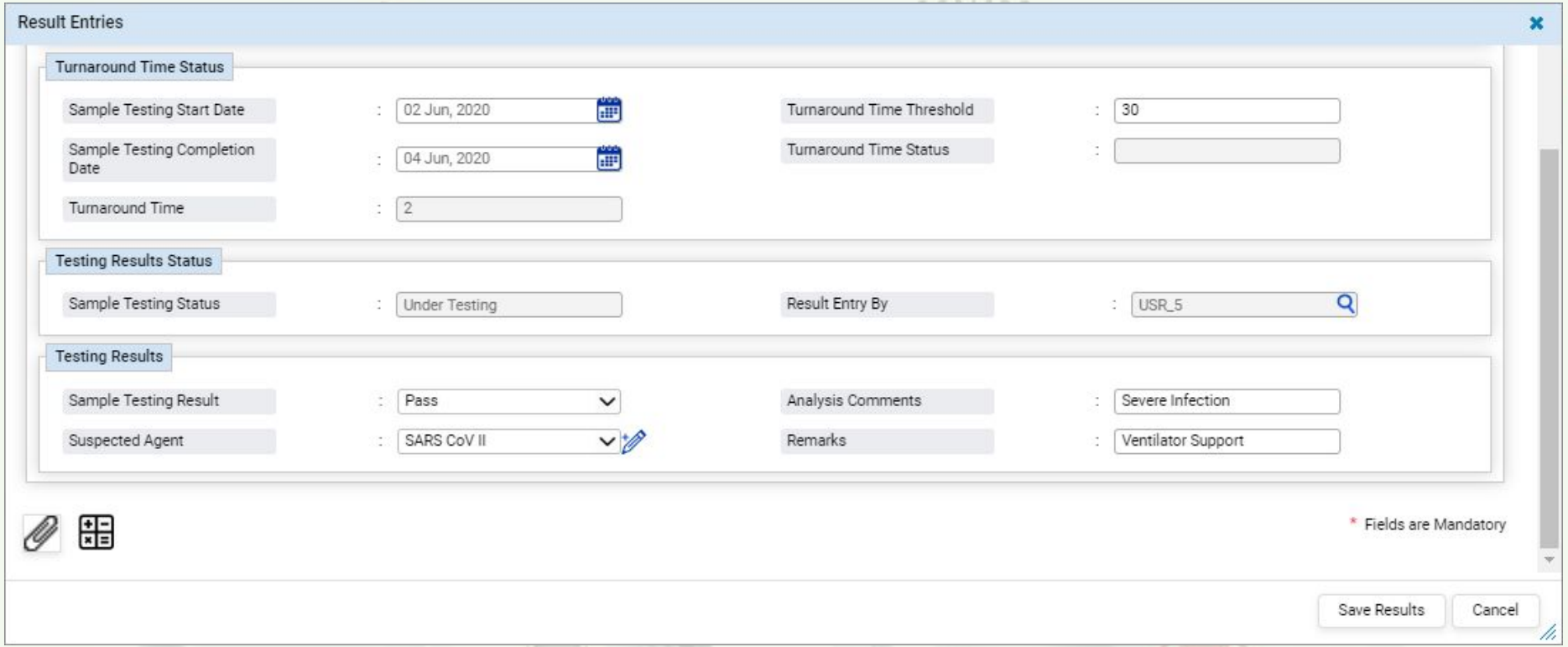
Deidentifying Samples



	Subject ID	State Generate nCoV ID (PUI ID)	Name	DOB	Age	Travel History	Pre-existing Medical Conditions	Quarantine Duration	Under Observation	
1	CV19_20	BS8907126543	xxxxx	07 Jun, 1960	60	Traveled to Madrid from Biscay Doctor in Profession	Neurological Issues	0 days	Yes	Univers
2	CV19_19	WS2154360987	xxxxx	11 Jul, 1950	70	Traveled locally Medical Shop owner	Diabetes Mellitus, Neurological Issues	0 days	Yes	Londor
3	CV19_18	IS3452189607	xxxxx	05 Aug, 1955	65	Traveled Locally Shop Owner	Chronic Lung Disease, Asthma, Diabetes Mellitus	20 Days	Yes	Khojas
4	CV19_17	AD5098764132	xxxxx	09 Dec, 1970	50	Traveled Locally School teacher	Renal Disease, Immmunocompromised	0 Days	Yes	Emam
5	CV19_16	AD2135469870	xxxxx	01 Jan, 2020	30	Traveled Locally for Office	Asthma, Emphysema	24 days	Yes	Acibad
6	CV19_15	OS6789054321	xxxxx	05 Apr, 1988	32	Traveled to India from Japan University Student on Mar 11th, 2020	Asthma, Heart Disease	6 days	Yes	Osaka
7	CV19_14	DU7890654321	xxxxx	08 Jan, 1979	61	Traveled from Japan to Ireland via Doha on Jan 28th, 2020	Asthma	15 days	Yes	Beacor
8	CV19_13	CA9807651234	xxxxx	03 Feb, 1980	40	Traveled to Texas from California on Mar 1st, 2020	Other Chronic Issue	16 days	Yes	Eden M
9	CV19_12	ND2341569807	xxxxx	28 May, 1992	27	Traveled Locally for Office and University	Diabetes Mellitus	14 days	Yes	Dougla
10	CV19_11	SD9870651234	xxxxx	10 Oct, 1995	25	Traveled locally for Office	Emphysema	0 days	Yes	Marsha
11	CV19_10	OH1345627890	xxxxx	17 Apr, 2000	20	Traveled locally and University Student	Emphysema	14 days	Yes	Barnes
12	CV19_9	CH9870635421	xxxxx	02 May, 2001	19	Traveled Locally and University student	Asthma	0 days	Yes	Swedis
13	CV19_8	CA1234569807	xxxxx	08 Sep, 1974	46	Travel from Chicago to Spain on Mar 25, 2020	Diabetes Mellitus	5 days	Yes	Hospit
14	CV19_7	NY2345160978	xxxxx	20 Jul, 1970	50	Traveled from India to New York Via Dubai on Mar 10, 2020	Liver Disease	12 Days	Yes	James
15	CV19_6	IN9087645321	xxxxx	10 May, 1992	28	Traveled Locally in Greenwood Indiana	Current Smoker	8 days	Yes	In Hou
16	CV19_5	HN6789054321	xxxxx	17 Nov, 1975	45	Traveled Locally in Buses and Tubes for Office in Wuhan	Diabetes Mellitus	0 days	Yes	Wuhan
17	CV19_4	SI7890643215	xxxxx	05 Jun, 2000	20	Traveled from Catania to Florence by train on Feb 20	Emphysema	9 days	Yes	San Fil
18	CV19_3	DE6543210987	xxxxx	02 Apr, 1980	40	Traveled Locally in London	Asthma	0 days	Yes	Buxton
19	CV19_2	NJ1234509876	xxxxx	24 Aug, 1955	65	Traveled to New Jersey from Beijing via Qatar on Jan 20, 2020	Neurological Issues, Current Smoker	22 days	Yes	Garfiel

CloudLIMS
Empowering Labs

Tracking TAT



CloudLIMS
Empowering Labs

Generating Templated Reports

MedLAB

COVID-19 TEST

Final Patient Report

Subject Information

Subject ID:	CV19_1	**State Generate nCoV ID (PUI ID):**	LD5643289017	**Name:**	Paula Jackson	**DOB:**	08 Aug, 1980
Age:	40	**Covid19 Suspected:**	Yes	**Disease Onset:**	10 Feb, 2020	**Address:**	123 London street
Country:	London	**Gender:**	Male	**Doctor's Name:**	Dr Paolo Carol		

Sample Information

Sample ID:	BAL_1	**Collection Time:**	9 AM
Repeat Sample:	No	**Collection Date:**	11 Feb, 2020
Collection Site:	London State General Hospital	**Collected By:**	Dr Elly

Test Information: Covid 19/ ELISA SEROLOGICAL

Test ID	Test Name	Method
ELSLCV_2	Test 02 IgG IgM	ELISA SEROL

Analytes and Results: Covid 19/ ELISA SEROLOGICAL

Analyte Group	Analyte Name	Observed Value	Flag	Minimum	Maximum
CV19 ELISA SEROL	IgG	0.984	Infected	0.441	1.832
CV19 ELISA SEROL	IgM	0.192	Infected	0.141	0.661

Other Information

Suspected Agent	Analysis Comments	Remarks
SARS CoV II	Coronavirus Infected	Isolation

© 2020 COVID19 LIMS. All Rights Reserved.

MedLAB

Test Methodology

Genotyping by PCR-based enrichment and next-generation sequencing or by array-based evaluation of multiple molecular probes. SARS Co-V2 assay includes the CDC EUA assay as well as a laboratory developed test based on the WHO methodology.

Disclaimer

This test was developed, and its performance characteristics cleared or approved by the FDA.The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

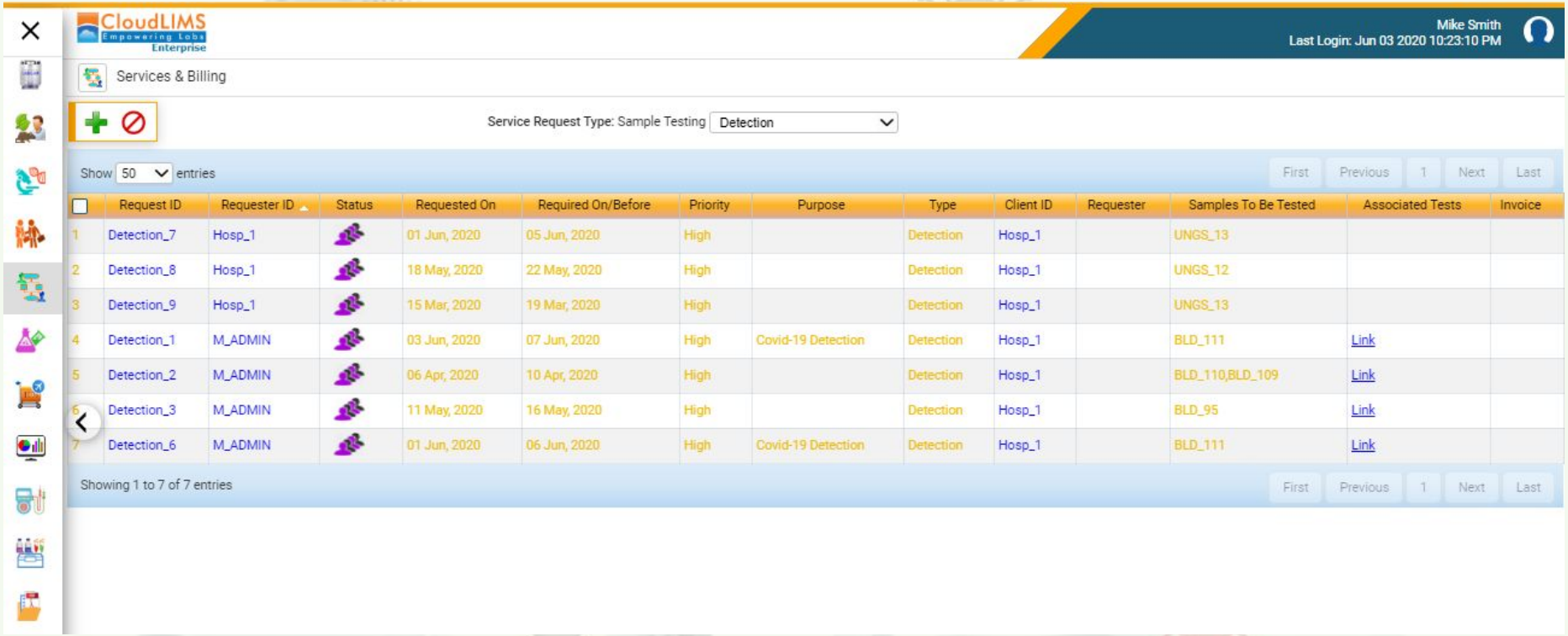
Risks and Limitations

The certified testing laboratory has standard and effective procedures in place to protect against technical and operational problems. However, such problems may still occur. The testing laboratory receives samples collected by patients and physicians. Problems in shipping to the laboratory or sample handling can occur, including but not limited to damage to the specimen or related paperwork, mislabeling, and loss or delay of receipt of the specimen. Laboratory problems can occur that might lead to inability to obtain results. Examples include, but are not limited to, sample mislabeling, RNA contamination, uninterpretable results, and human/testing system errors. In such cases, the testing laboratory may need to request a new sample. However, upon re-testing, results may still not be obtainable.

© 2020 COVID19 LIMS. All Rights Reserved.

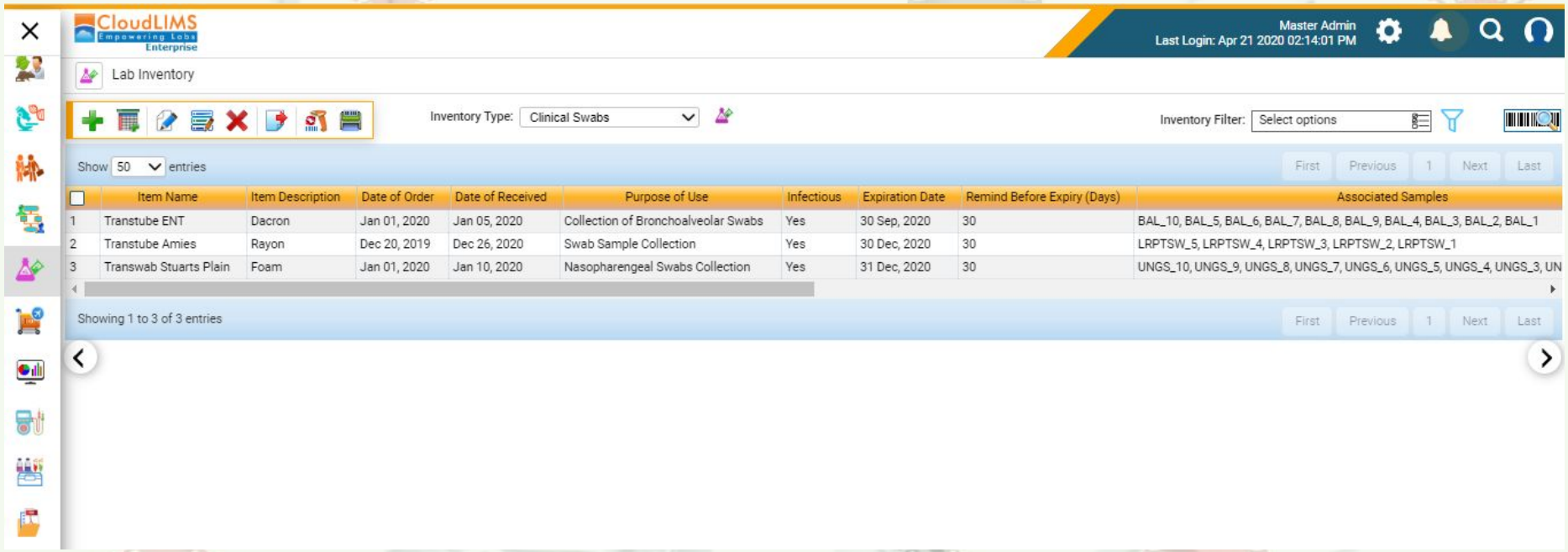
CloudLIMS
Empowering Labs

Services & Billing



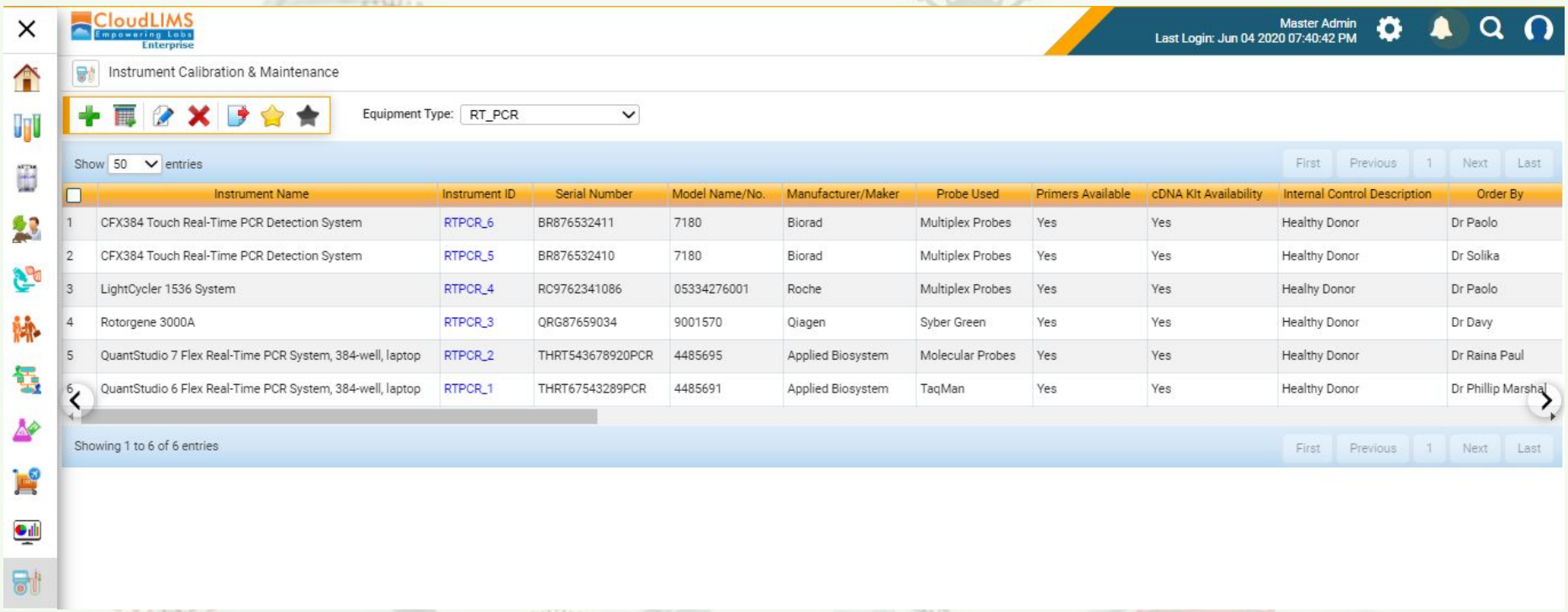
CloudLIMS
Empowering Labs

Managing Inventory (CLIA Requirement)



CloudLIMS
Empowering Labs

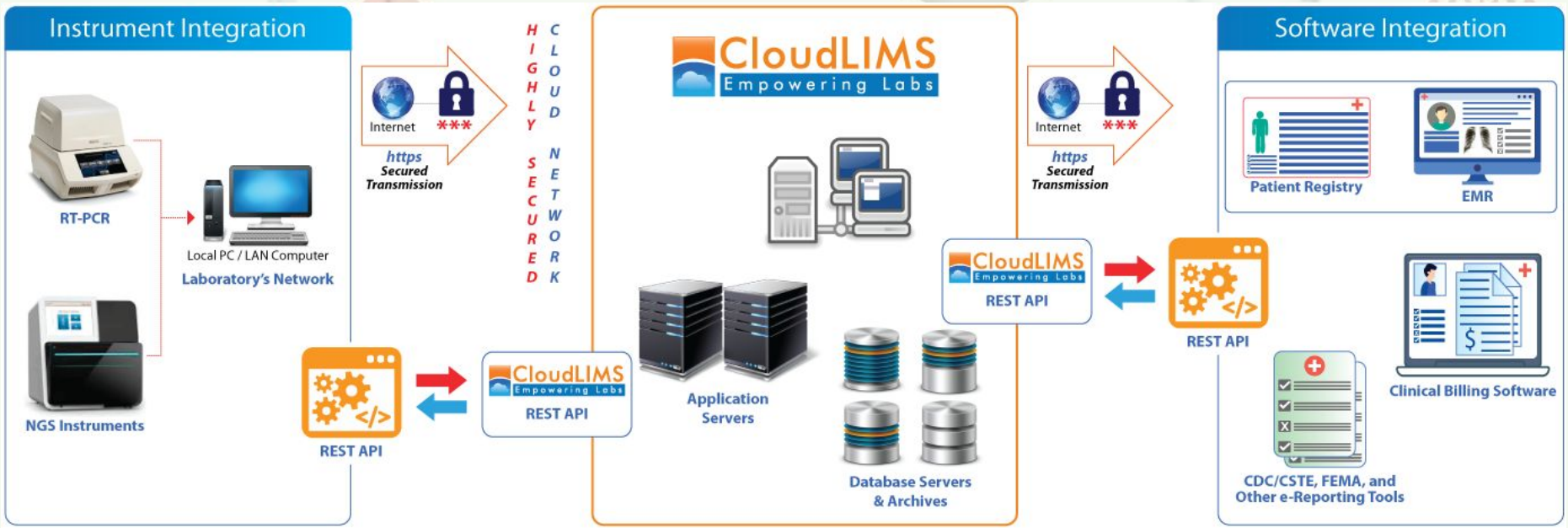
Maintaining Instruments (CLIA Requirement)



	Instrument Name	Instrument ID	Serial Number	Model Name/No.	Manufacturer/Maker	Probe Used	Primers Available	cDNA Kit Availability	Internal Control Description	Order By
1	CFX384 Touch Real-Time PCR Detection System	RTPCR_6	BR876532411	7180	Biorad	Multiplex Probes	Yes	Yes	Healthy Donor	Dr Paolo
2	CFX384 Touch Real-Time PCR Detection System	RTPCR_5	BR876532410	7180	Biorad	Multiplex Probes	Yes	Yes	Healthy Donor	Dr Solika
3	LightCycler 1536 System	RTPCR_4	RC9762341086	05334276001	Roche	Multiplex Probes	Yes	Yes	Healhy Donor	Dr Paolo
4	Rotorgene 3000A	RTPCR_3	QRG87659034	9001570	Qiagen	Syber Green	Yes	Yes	Healthy Donor	Dr Davy
5	QuantStudio 7 Flex Real-Time PCR System, 384-well, laptop	RTPCR_2	THRT543678920PCR	4485695	Applied Biosystem	Molecular Probes	Yes	Yes	Healthy Donor	Dr Raina Paul
6	QuantStudio 6 Flex Real-Time PCR System, 384-well, laptop	RTPCR_1	THRT67543289PCR	4485691	Applied Biosystem	TaqMan	Yes	Yes	Healthy Donor	Dr Phillip Marshal

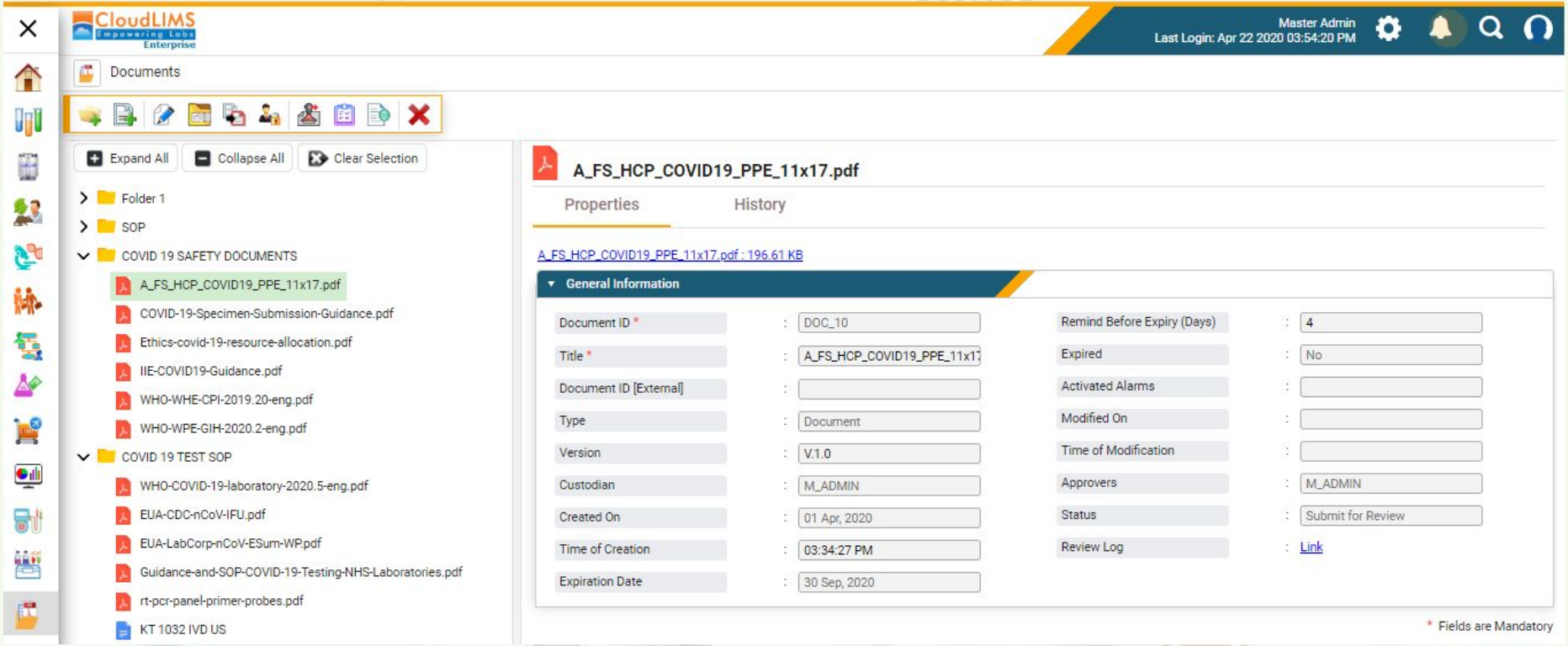
CloudLIMS
Empowering Labs

Importing Test Results



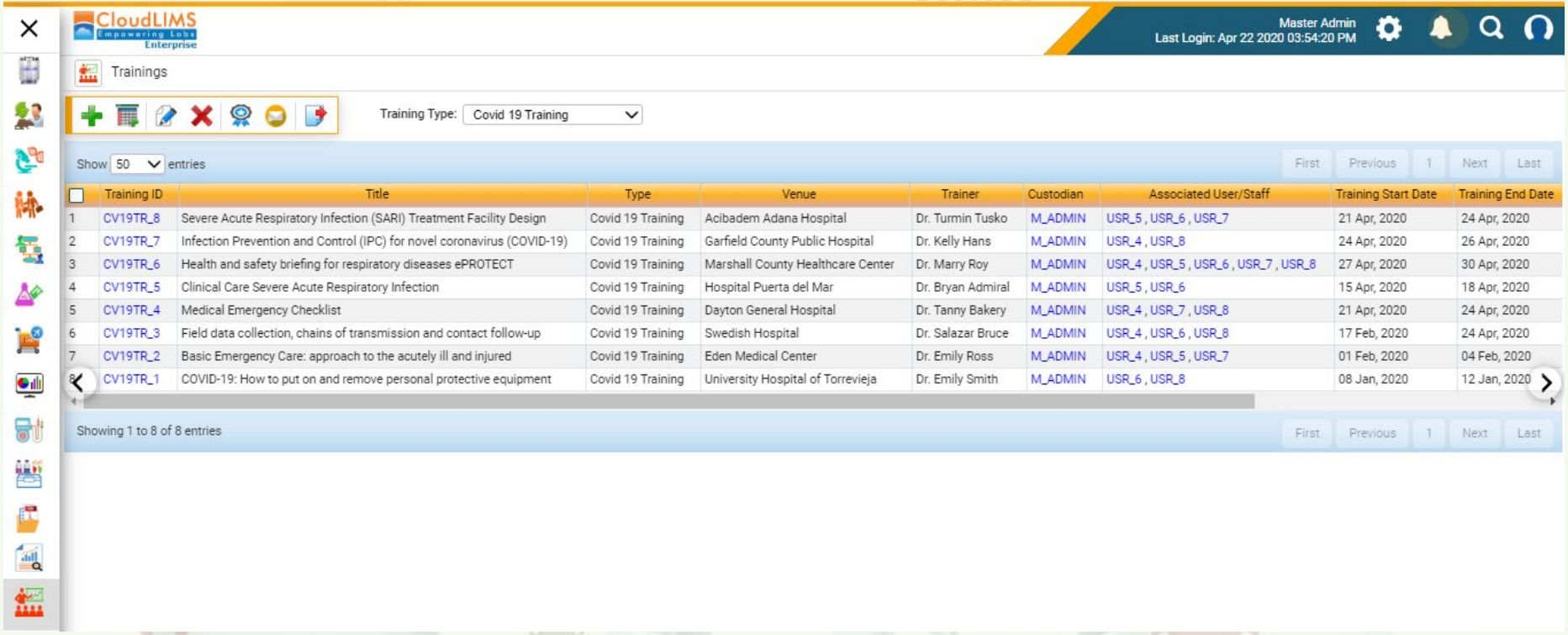
CloudLIMS
Empowering Labs

Managing Documents (ISO 15189 Requirement)



CloudLIMS
Empowering Labs

Training Personnel (ISO 15189 Requirement)



CloudLIMS
Empowering Labs

LIMS Benefits

1. Easily track sample's journey in the lab, right from collection till disposal
2. Ensure patient confidentiality to follow HIPAA guidelines
3. Integrate with instruments to load accurate test results with ease
4. Manage instrument maintenance and calibration schedules
5. Maintain quality measures via proper documentation and staff training
6. Generate custom test reports to comply with the FDA & CDC reporting guidelines

CloudLIMS
Empowering Labs

Thank You!

www.cloudlims.com
+1-302-789-0447
support@cloudlims.com

CloudLIMS
Empowering Labs