COVID-19 Serology Control Panel (CSCP)

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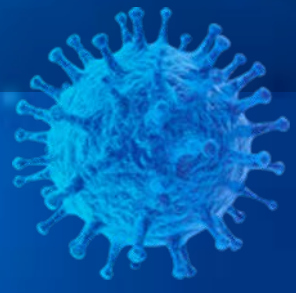

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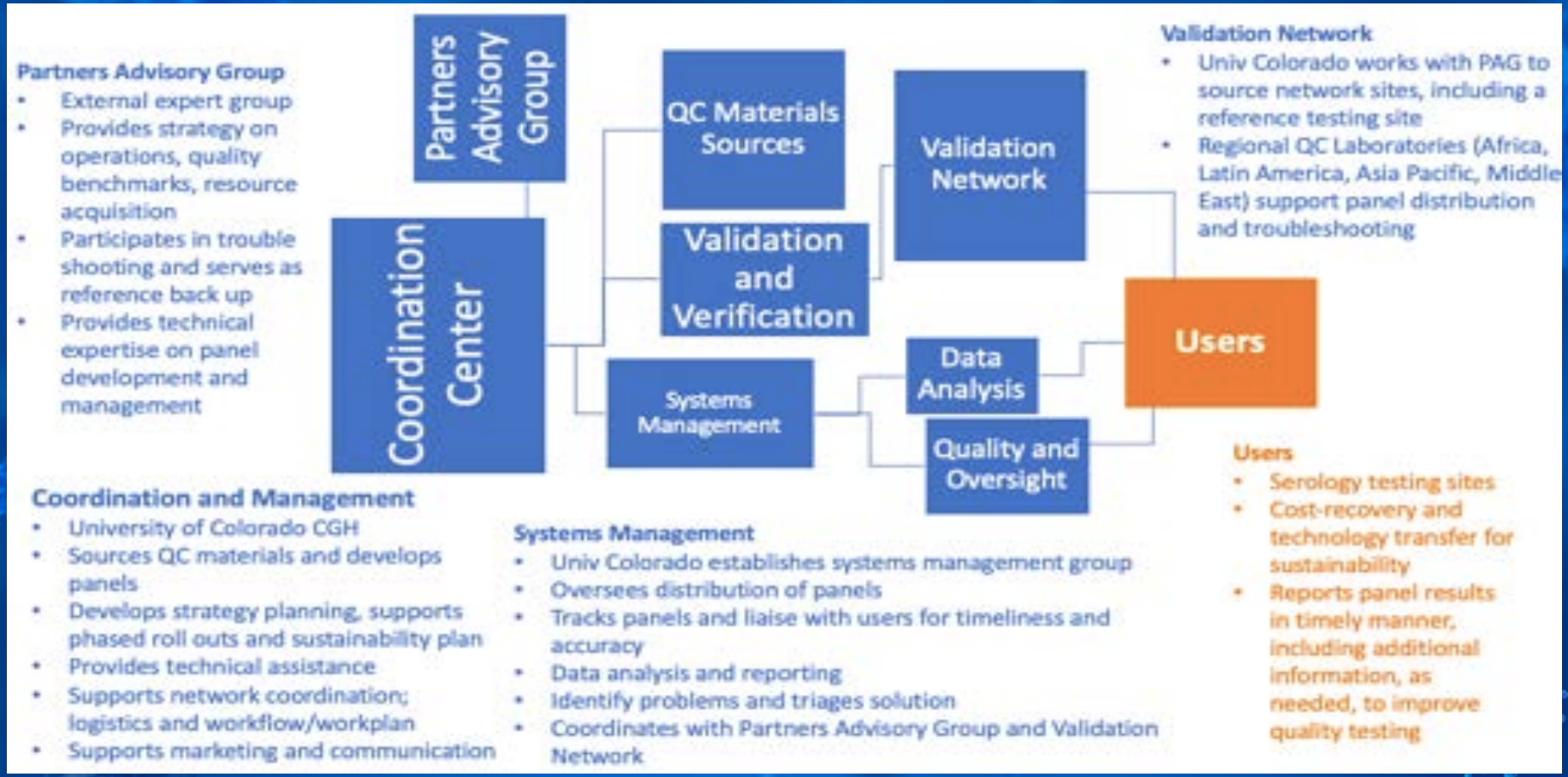
How this came about (March 2020):

- No coordinated infrastructure exists that allows for access to quality serological reference materials
- At least 145 COVID-19 antibody test kits were listed for with no quick way to assess their quality (the list grew to over 400)
- Diagnostic test unreliability in general was leading to deterioration of trust in the results
- Recognize the need to improve and maintain quality laboratory test

Guiding Principles

- Equitable access and fairness - Providing equal access to all regions, both public and private testing facilities, for the improvement of COVID-19 serological testing
- Collaboration and support – Working with organizations and institutions to support a global resource for quality COVID-19 serological testing
- Transparency and sharing – Sharing of information and protocols for better understanding and improvements to the quality of COVID-19 testing
- Sustainability and country ownership – Create a virtual biorepository and to transfer technology to countries and organizations to bring access to quality materials



A conceptual design of a more sustainable and enduring infrastructure

Objectives

- Provide a quick overview of the CSCP.
- Define the process used to develop the CSCP.
- Discuss the validation of the CSCP.
  - Share preliminary findings
- Discuss our current standing and next steps.

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Overview

- The CSCP is a kit of 5 well characterized and validated Dried Tube Specimens for labs to use as a resource to:
  - COVID-19 Serology Test Comparisons
  - Quality Control
  - Training Material
  - Multi-Center Research Studies

- **Goal:** Track the performance of COVID-19 serology diagnostic tests for quality and consistency.

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What are Dried Tube Specimens (DTS)?

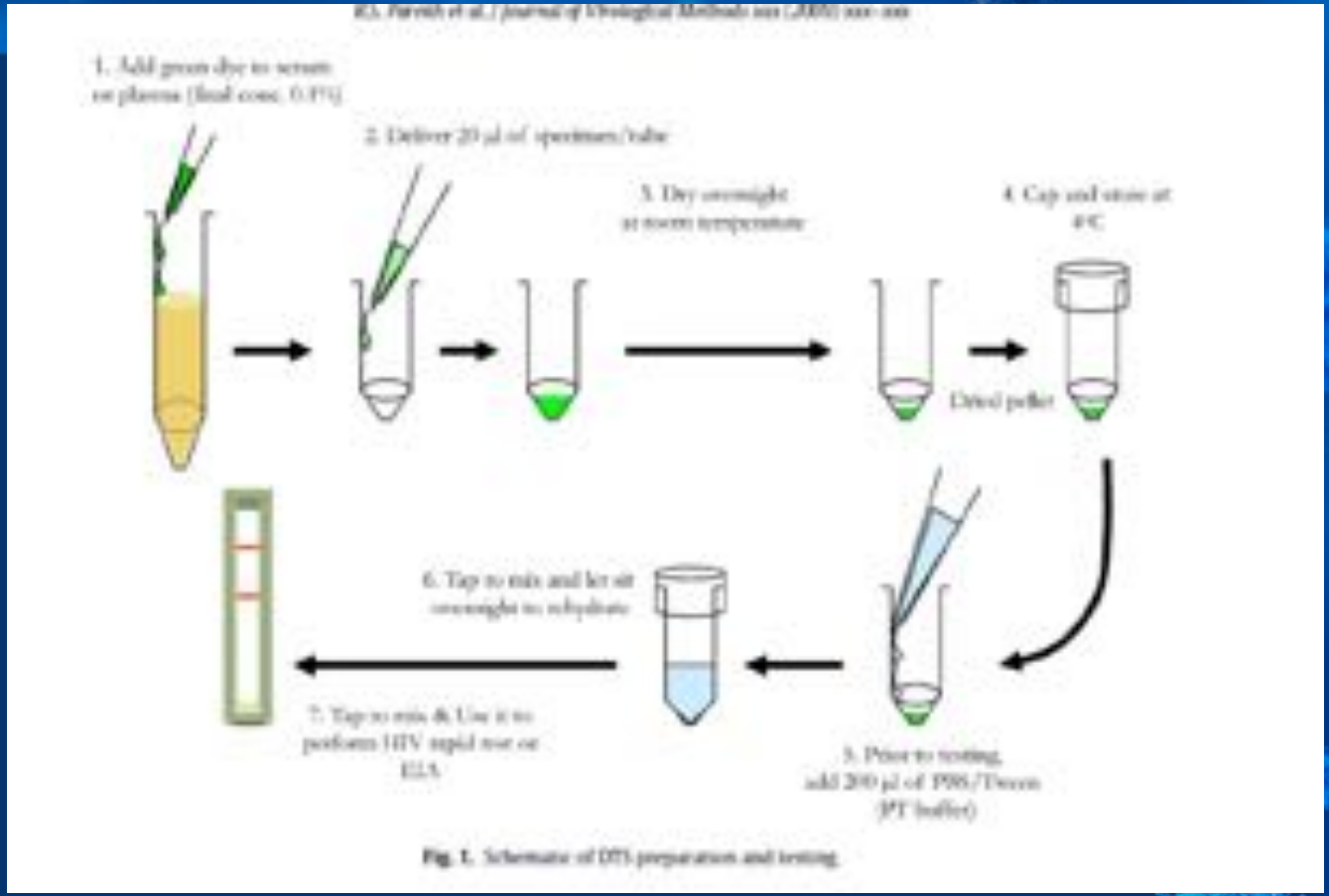

Fig. 1. Schematic of DTS preparation and testing.

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Benefits of DTS

- Kit is stable at a wider temperature range.
  - ~1 month between -20C and 37C
- Simplifies sample transport and storage logistics as there is no cold chain requirement

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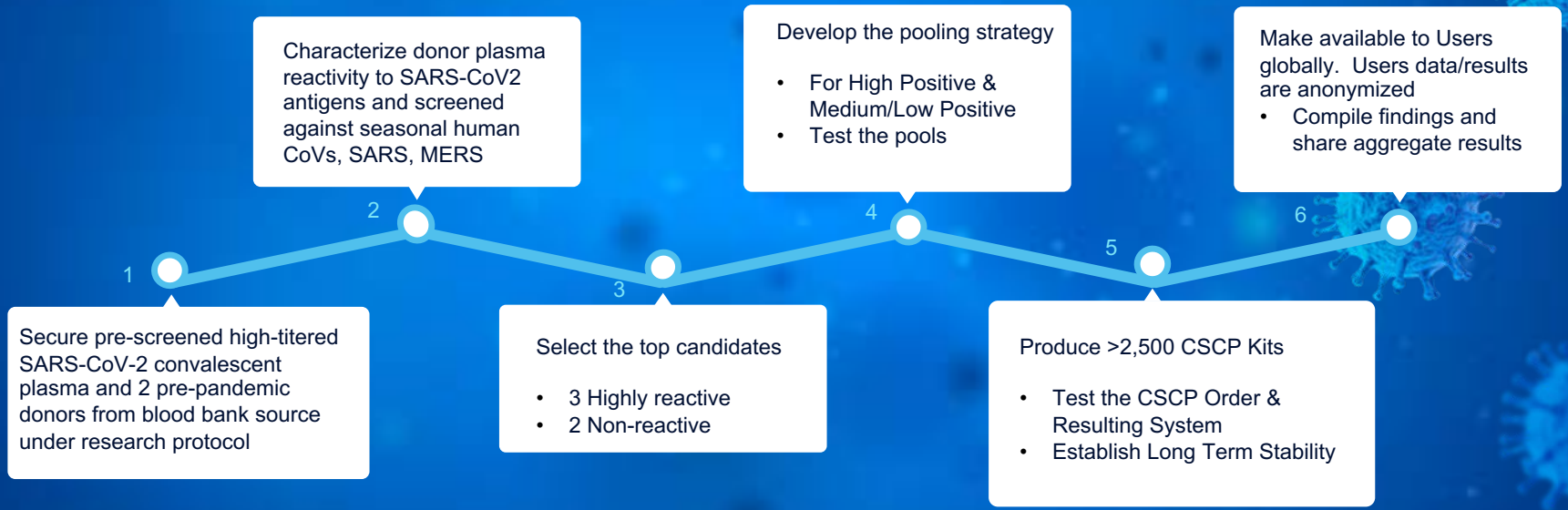
CSCP Development & Design



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CSCP Evaluation Group

	Method(s) used:	Antibody(s):	Antigen(s):
Lab 1	ELISA HE-ELISA	IgM IgG	Nucleocapsid
Lab 2	ELISA	IgG	Nucleocapsid Receptor Binding Domain
Lab 3	Focus-Reduction Neutralization Test	Total Ig	Total Virus
Lab 4	Pseudo-Virion Neutralization Assay	Total Ig	Spike
Lab 5	Nano-bead microarray	IgG	Nucleocapsid Receptor Binding Domain

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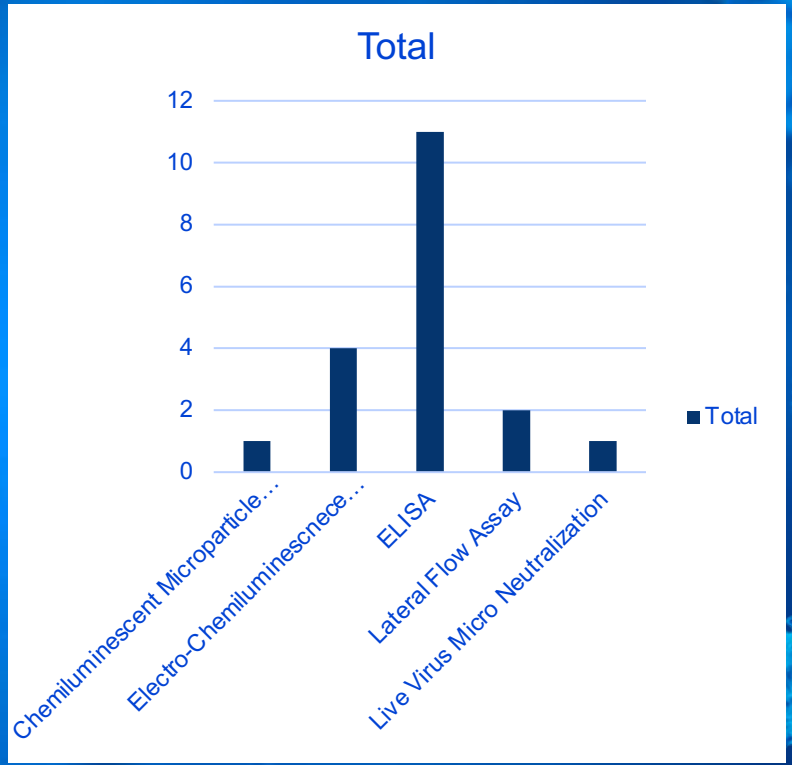
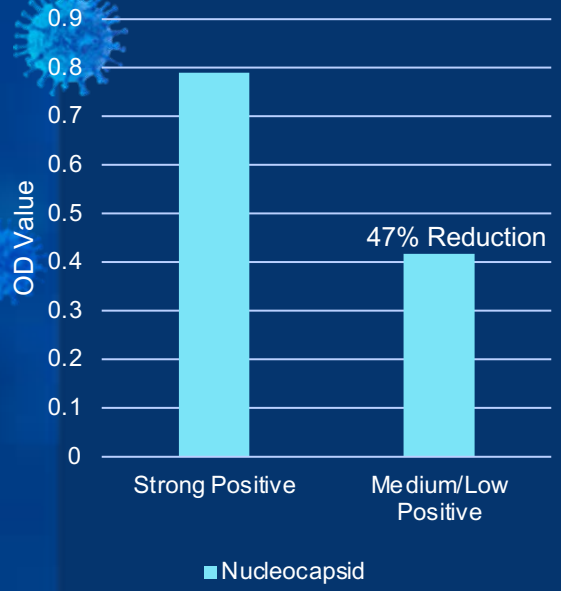
- Our results so far represent a small number of tests being deployed in research and diagnostic testing, but mirrors the types of platforms being used

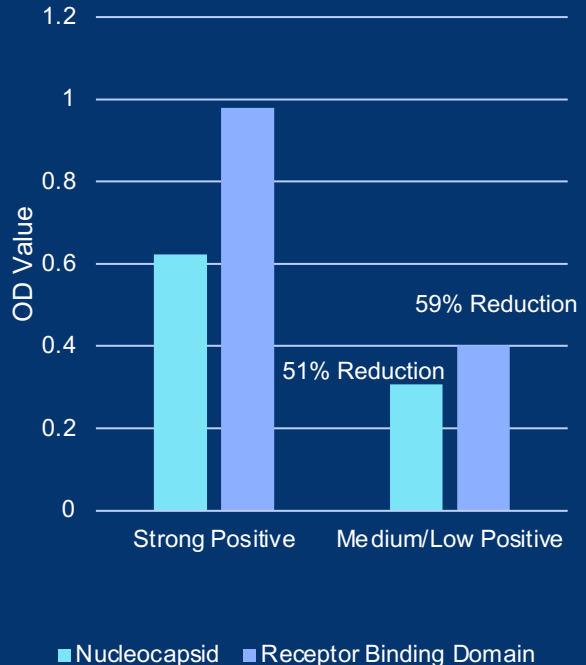


Plasma Pooling Results

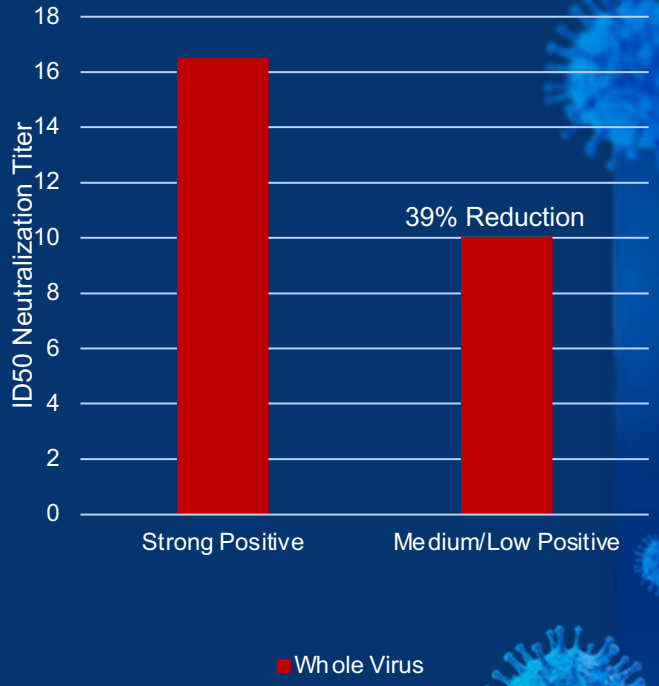
Lab 1 ELISA: High vs Medium/Low Positive Pooled Plasma Results



Lab 2 ELISA: High vs Medium/Low Positive Pooled Plasma Results



Lab 3 FRNT: High vs Medium/Low Positive Pooled Plasma Results



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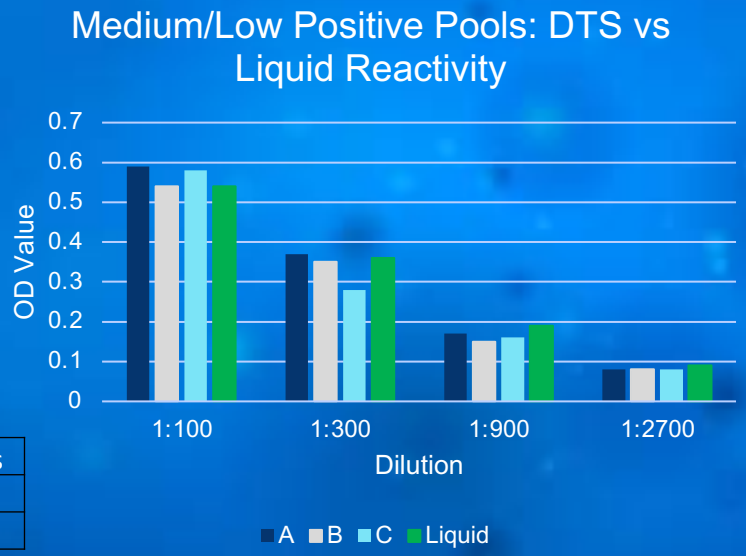
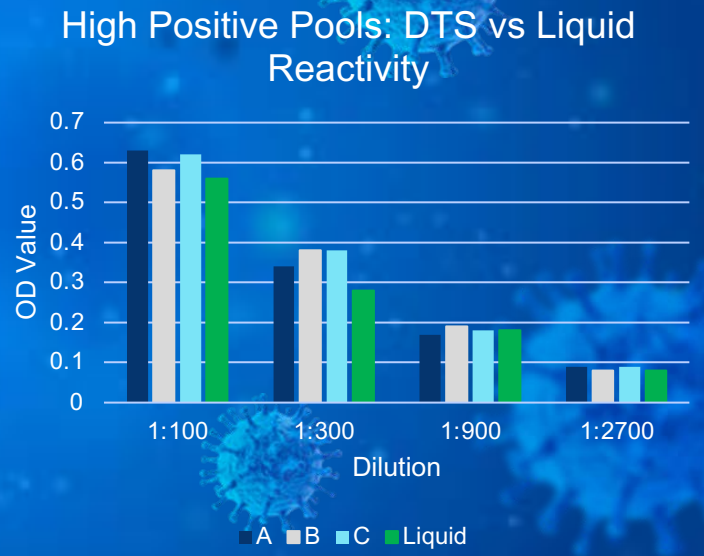
Liquid vs Dried Tube Specimen (DTS) Comparison

- Compared using the Epitope Diagnostics COVID-19 serology platform.
- DTS undergo 1:10 dilution during rehydration step.
- Liquid specimen comparable to DTS

	OD values
Positive Cut-off	0.29
Negative Cutoff	0.24





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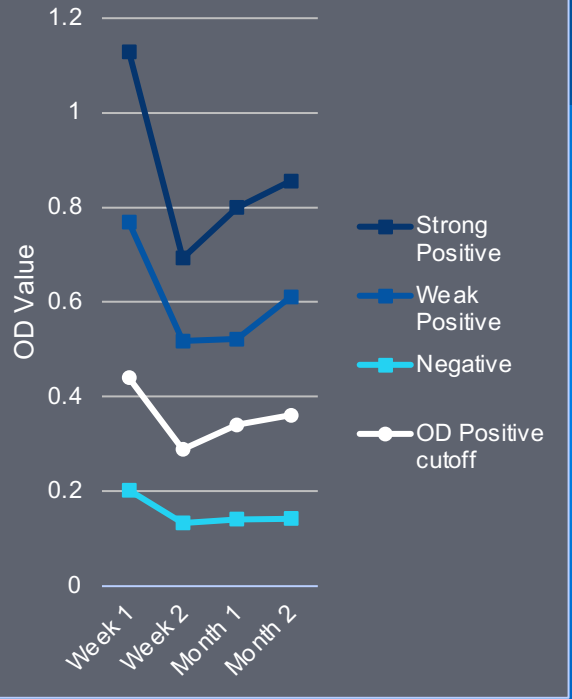
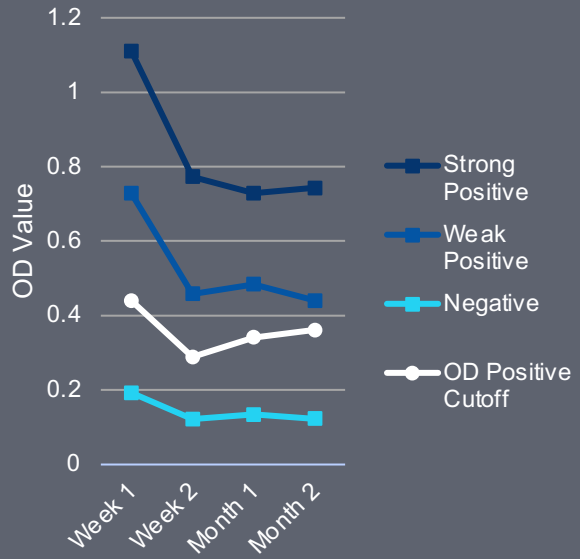
Long Term Stability Results

-20C Long Term Stability Results

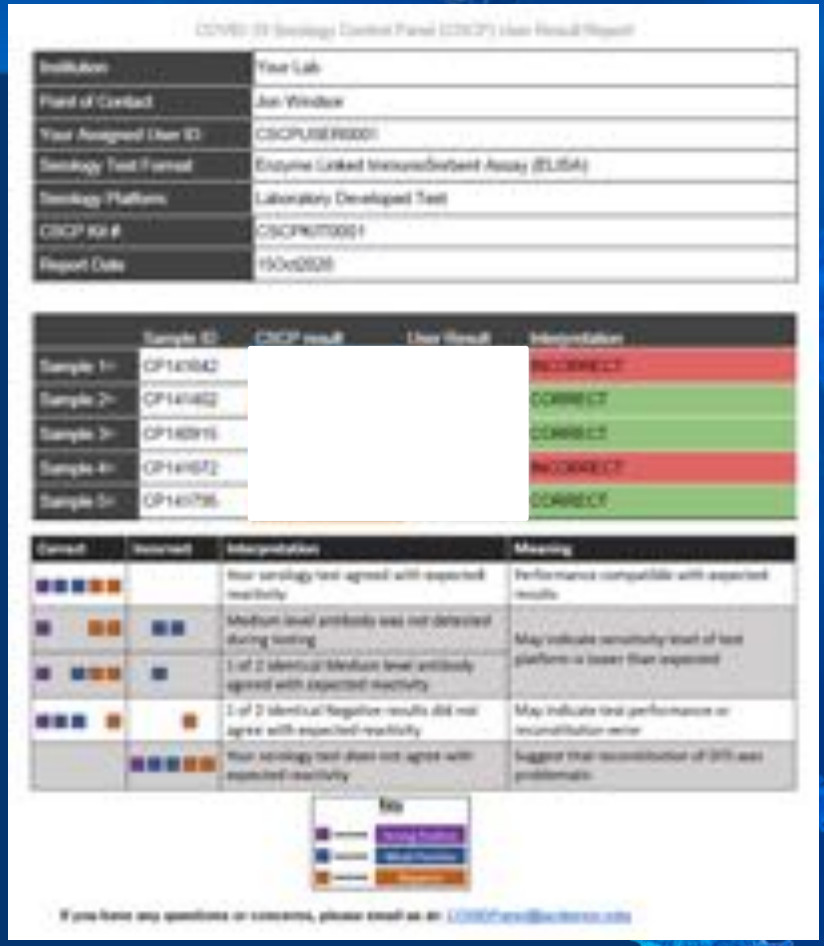


Ambient Temperature (22-25C) Long Term Stability



37C Long Term Stability

Example CSCP User Result Form



Institution	Your Lab
Point of Contact	Jon Window
Your Assigned User ID	CSCPUSER0001
Serology Test Format	Enzyme Linked Immunosorbent Assay (ELISA)
Serology Platform	Laboratory Developed Test
CSCP Kit #	CSCPKIT0001
Report Date	15Oct2020

	Sample ID	CSCP result	User Result	Interpretation
Sample 1=	CP1416042			INCORRECT
Sample 2=	CP1414452			CORRECT
Sample 3=	CP1402915			CORRECT
Sample 4=	CP1416572			INCORRECT
Sample 5=	CP1415795			CORRECT

Correct	Incorrect	Interpretation	Meaning
		Your serology test agreed with expected reactivity	Performance compatible with expected results
		Medium level antibody was not detected during testing	May indicate sensitivity level of test platform is lower than expected
		1 of 2 identical Medium level antibody agreed with expected reactivity	
		1 of 2 identical Negative results did not agree with expected reactivity	May indicate test performance or reconstitution error
		Your serology test does not agree with expected reactivity	Suggest that reconstitution of kit was problematic

Key

If you have any questions or concerns, please email us at: CSCP.test@jacklabs.edu

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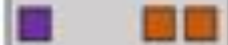
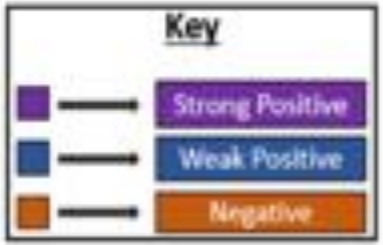
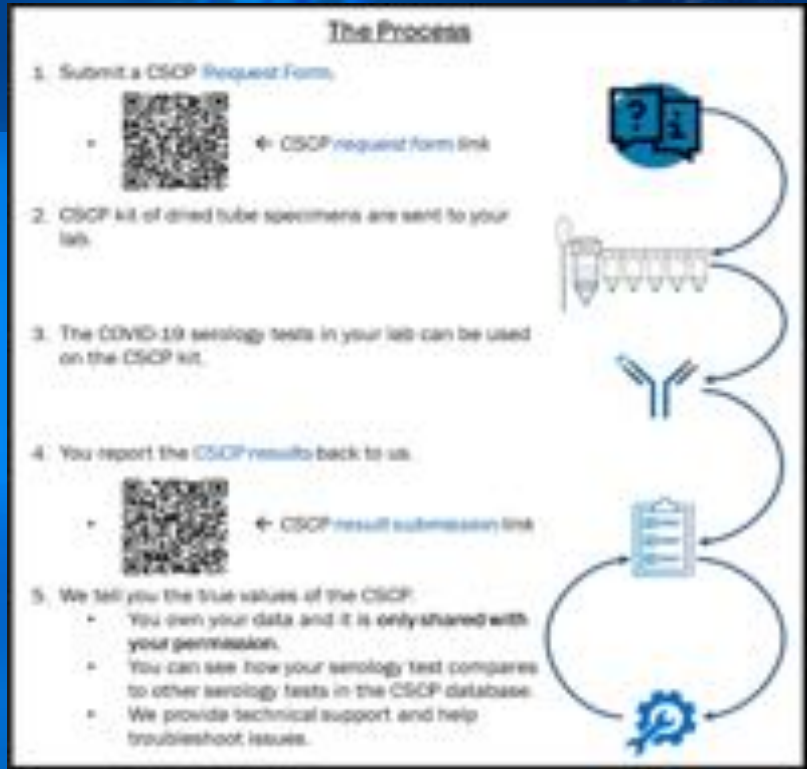
Correct	Incorrect	Interpretation	Meaning
		Your serology test agreed with expected reactivity	Performance compatible with expected results
		Medium level antibody was not detected during testing	May indicate sensitivity level of test platform is lower than expected
		1 of 2 identical Medium level antibody agreed with expected reactivity	
		1 of 2 identical Negative results did not agree with expected reactivity	May indicate test performance or reconstitution error
		Your serology test does not agree with expected reactivity	Suggest that reconstitution of DTS was problematic



Current Status of the COVID-19 Serology Control Panel

- We have launched for Users
- If Interested, follow the instructions→
- Or visit the following link to request a kit for your lab:
  https://docs.google.com/forms/d/e/1FAIpQLSdLHPMGINTJgdrkp2BqISx3Dfkzar0nW4wvGroOoGcF_WO8sw/viewform
- The University of Colorado Center for Global Health website:
  https://coloradosph.cuanschutz.edu/research-and-practice/centers-programs/globalhealth/research-projects/global-infectious-disease-consortium/home



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Here is what a CSCP Kit looks like

Assembled

Disassembled

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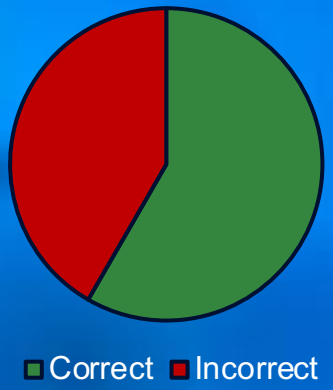
CSCP Status
&
Next Steps

CSCP User Results So Far...

Strong Positive

Medium/Low Positive



Negative

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Next steps:

- Continuous accretion and analysis of CSCP kit results.
  - Test in parallel with other standards (including NIBSC International Standards)
- Embed CSCP kits as part of lateral flow test kits being rolled out in African region
  - Coordinating with grassroots labs
- Creating other screening panels: Zika, dengue
- Launch a virtual biorepository as a global good infrastructure
  - Hub: Virtual Biorespository, https://globalbiorepository.tghn.org/

Questions?

Contact Information:

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