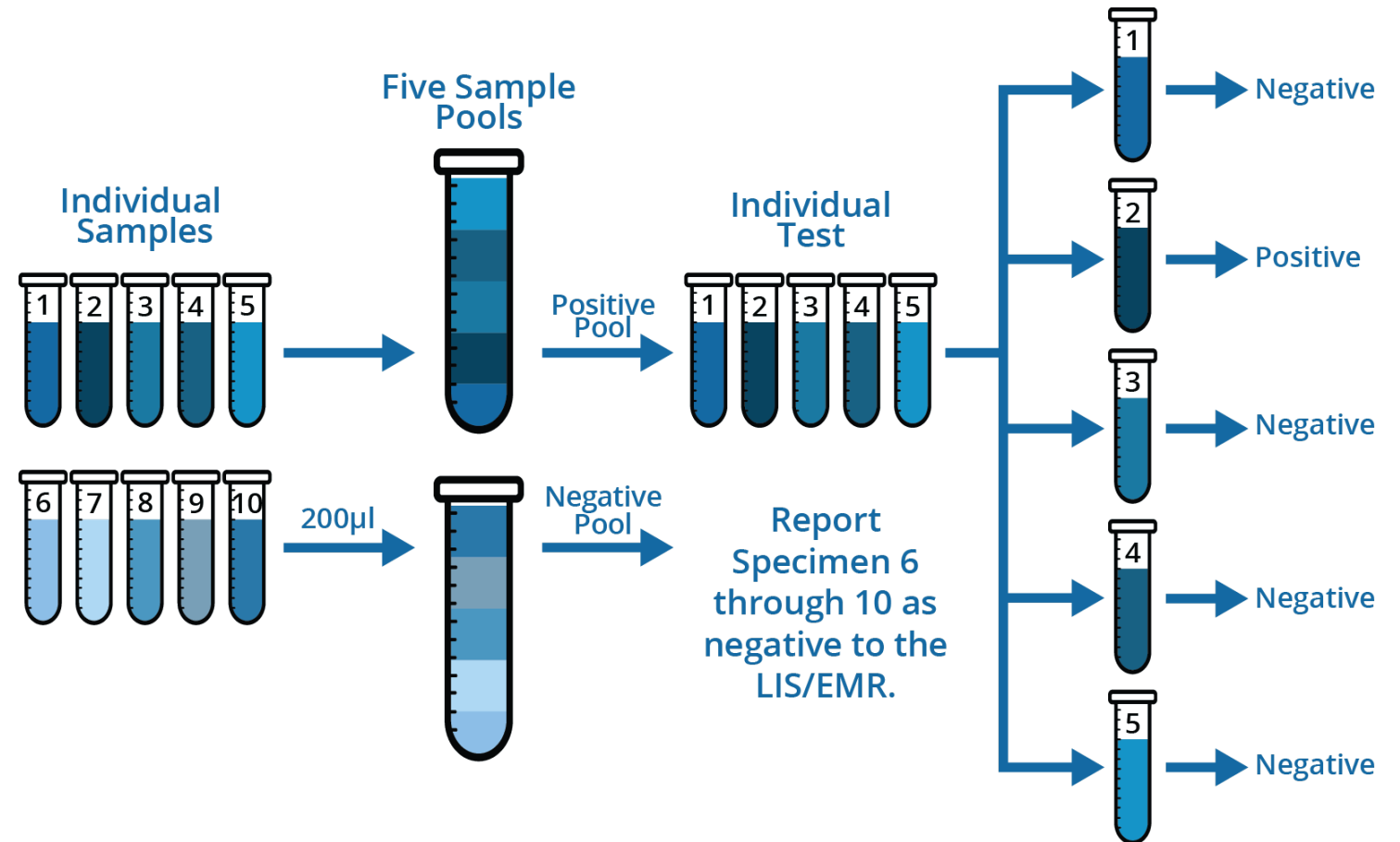




Instrument Manager Pooled Specimen Testing Solution

Pooling Basics

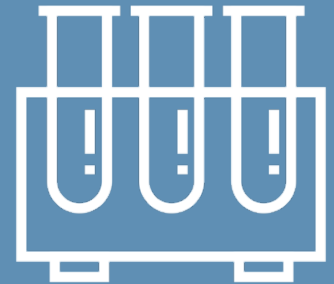
- Labs define desired pool size (e.g. 5 specimens)
- Positive values are reflex tested to confirm positive specimen(s)
- Negative pool values are copied to pool constituents for reporting to the LIS/EMR
- Note: This is an example. Sample size will vary based on SOP and Assay LOD. Coloration on samples and pools is for demonstrative purposes only.



IM Pooled Specimen Testing

Key functionality:

- Licensable feature in IM v8.14 and greater
- Minimal changes needed for LIS and instrument
- User Interface for Pool creation in IM with configurable maximum Pool sizes
- Ability to create instrument-ready barcode for the Pool
- Propagation of negative pool results to individual constituent Specimen IDs
- Ability to run individual specimens when pool result is positive without user intervention for ordering.
- Traceability of Pool ID and Pool result with individual Specimen IDs.



Pool Configuration

IM Data Innovations LLC Pooling Solution Configuration

Driver Configuration

Pooling Configuration Table

IM Test Code	Pool Order Test Code	Connection / Cluster	Pool Size	Negative Result Value
COVID19	COVID19_POOL	c8000	5	neg,NEG,-ve

Auto Generate Pool ID

Pool Barcode Prefix:

Close

- Users will be able to define if a Site defined Pool ID will be used or an IM generated Pool ID
- Users will designate specific instruments or clusters to be used for pooling
 - Each IM test/instrument(cluster) combination used for pooling will have its own maximum pool size configured
 - Each IM test/instrument(cluster) combination used for pooling will have a specified Pool order test code to be used in mapping on the instrument configuration.
 - Each IM test/instrument(cluster) combination will have designated values that will trigger the Negative Pool workflow.

Pool Creation

IM Data Innovations LLC Pooling Solution Utility

Pool Parameters

Select Connection / Cluster to Run Pooled Sample: - None -

Pool ID: (Auto Generated)

Settings

Print Pool Barcode when pool is created

Pool Information

Add Specimens to Pool to view Pool Information

Specimen ID	Patient ID	Patient Name	Date of Birth
*			

Create Pool | Start New Pool | Reprint Pool Barcode

- Pool creation will be a utility screen in IM accessed from the status screen. Multiple users can access the utility at the same time.
- The user may choose a connection(cluster) for Pool creation. Only instruments defined in the Pool Configuration will display.
- The user may choose to print or reprint a barcode to label the Pool tube. This barcode will be instrument ready identifier with an available order once the pool is created.

Pool Creation

The screenshot shows the 'Data Innovations LLC Pooling Solution Utility' window. It is divided into several sections:

- Pool Parameters:** Includes a dropdown for 'Select Connection / Cluster to Run Pooled Sample' (set to 'c8000') and a 'Pool ID' field (set to 'POOL2372020000009').
- Settings:** A checkbox for 'Print Pool Barcode when pool is created' is checked.
- Pool Information:** Displays 'Pool Size' (5), 'Pool Fluid' (SER), and 'Ordered Test Code' (COVID19).
- Table:** A table with columns for Specimen ID, Patient ID, Patient Name, and Date of Birth. It contains two rows of data for specimen IDs 006003 and 006004, both with Patient ID 0101 and Patient Name 'Bear,Yogi,L', and Date of Birth 02/11/1978.
- Buttons:** 'Create Pool', 'Start New Pool', and 'Reprint Pool Barcode' are visible at the bottom.
- Status Bar:** Displays 'Successfully Created Pool'.

- Users will scan in Specimen IDs to create a Pool. If it is a valid specimen, the Patient ID, Patient Name and DOB will populate the screen.
 - A variety of checks will happen in the background as the Pool is created:
 - Is the specimen assigned to another Pool?
 - Does the specimen have a qualifying test code for the instrument (cluster) chosen?
 - Are there additional test codes on this specimen?
 - Does the Pool ID exist as a Specimen ID or Patient ID in the IM system?
 - Does the specimen have an instrument query for the LIS test code?
- The test code and fluid code for the pool will be determined by the first specimen scanned into the pool
 - Specimens not matching the test code/fluid code of the first specimen will be rejected from the Pool
- Users will not be able to add more specimens than the maximum Pool size defined in the Pool Configuration.
 - The Pool size, Pool Fluid and Pool Test Code will be available for display

Negative Pool Workflow

- If results of the Pool are Negative:
 - The Negative Pool Workflow is determined when the Pool result matches a value defined in the Pool Configuration “Negative Result Value”
 - Pools will be deconvoluted and the result of the Pool will be assigned to the individual specimen.
 - Parent result will be set on the individual Specimen ID to the result of the Pool.
 - Each individual Specimen will have a “Test Reviewer’s Comment” set to “Negative Pool result”
- If the resulting instrument is not the defined connection(cluster) chosen at the time of Pool creation, the result will not be propagated to individual specimens and an error will be logged at the Parent Result stating “Pooled Instrument/Resulting Instrument mismatch”
- Rules may be written, and Specimen Management Workspace may be used for review of specimens.



Positive Pool Workflow



- If results of the Pool are NOT Negative:
 - Results will NOT be propagated to individual specimens. Those specimens will remain pending
 - Individual Specimen IDs will retain the original orders. The individual Specimen ID may be run on the instruments which the specimen was originally routed
 - Each individual Specimen in the Pool will have a Parent Result populated with “Initial Pool result inconclusive”
 - Specimen Management workspaces and rules may be used to assist customer workflow
 - Items such as Parent Barcode, Parent Result and the Prefix for the Pool ID have been designed for integration with rules and workspace filters

Traceability Features

- Pool IDs can be identified by the value “POOL” that will populate the Parent Barcode when the Pool is created.
 - IM assigned Pool IDs will have a prefix assigned for easy distinction of a Pool ID vs Specimen ID
- Each individual Specimen ID in a Pool will have
 - Parent Barcode populated with the Pool ID
 - Parent Result populated with the result of the Negative Pool
 - Test Reviewer’s Comment will be set to “Negative Pool result”



Example SM Workspace

IM Specimen Management Workspace - Pooled Specimen Workspace

Workspace Edit View Format Action Help

Pooled Specimen Workspace Off

Configure External Applications

POOLS Only Positive Pool

Specimen Worksheet

Parent Barcode ID

Specimen ID	Specimen Completion Status	Patient Name	Parent Result	Priority	Rack	Position
- POOL203020002						
Q13231	Pending	GREEN,GARY	Initial Pool result inconclusive			
Q13341	Pending	CASTO,CHILLIDAWG	Initial Pool result inconclusive			
- POOL203020001						
▶ Q13011	Complete	SMITH,JAMES	ND			
Q13121	Complete	JONES,JUDY	ND			
- POOL						
POOL203020001	Complete					
POOL203020002	Complete					
- (none)						
Q13891	Pending	LEAVES,AUTUMN				
Q13781	Pending	BALL,BEACH				
Q13451	Pending	CASTO,TINY				

Test Worksheet

Drag a column header here to group by that column.

Specimen ID	Connection Name	Test Status	Test Name /	Result	Result Date/Time	Test Reviewer Comment(s)	Error Name(s)	Test Comment(s)
*								
▶ Q13011	CB Instrument	Released	COVID19	ND	10/28/2020 7:16:07 AM	Not Detected per pool result		