



Strategies for Ensuring Consistency in Patient Results Across a Healthcare System

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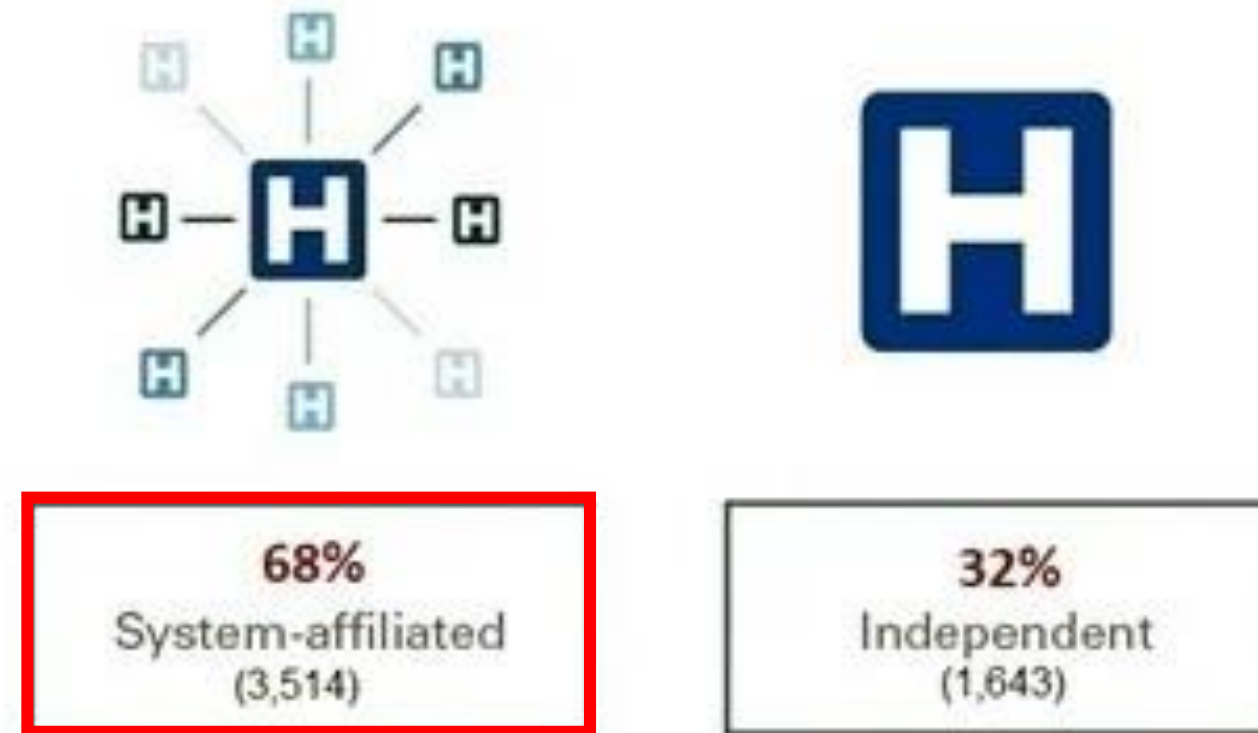
Learning Objectives

- Describe the advantages of standardization in clinical laboratory services, including but not limited to instrumentation, quality management and workflows.
- Address common challenges encountered in the process of implementing laboratory standardization.
- Implement practical approaches to assess the comparability of patient results within one healthcare system.



Fast Facts on U.S. Hospitals, 2023

Two-thirds of Community Hospitals are System-affiliated



Community Hospitals by System-affiliated vs Independent (Total 5,157), FY 2021

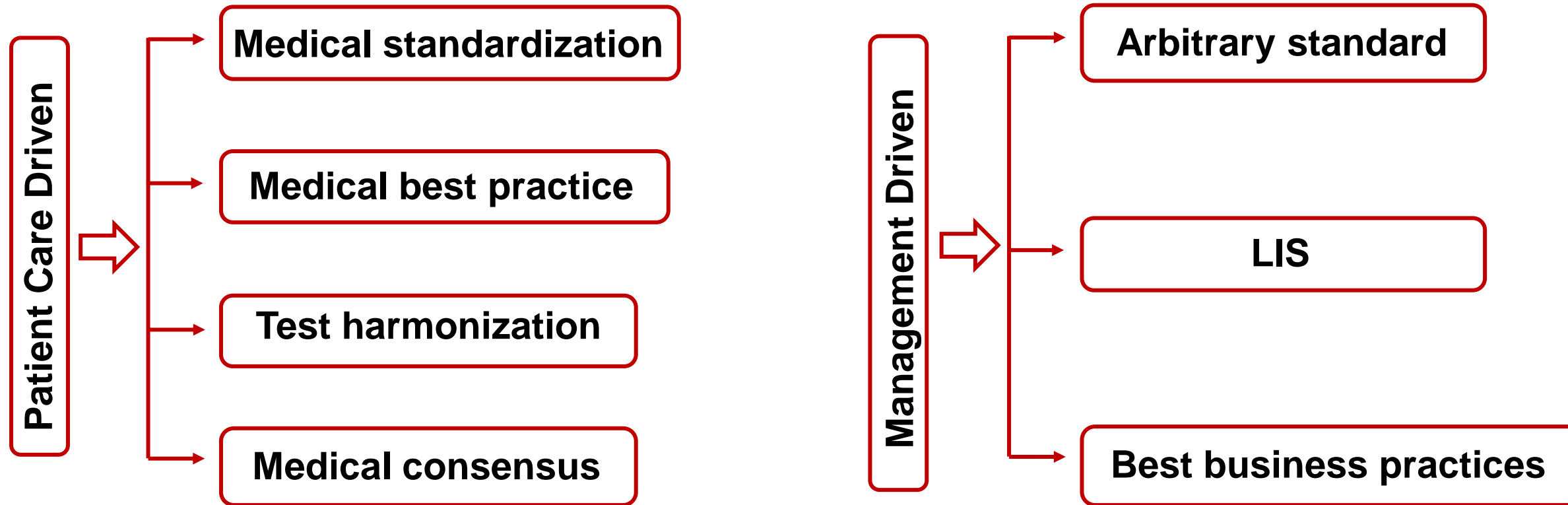
Source: American Hospital Association. Fast Facts on U.S. Hospitals, 2023

<https://www.aha.org/statistics/fast-facts-us-hospitals>

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Standardization Decisions



Prolactin - ng/mL (µg/L)	Y-01				Y-02				Y-03			
METHOD	N	MEAN	SD	CV%	N	MEAN	SD	CV%	N	MEAN	SD	CV%
Abbott Alinity ci series	175	29.80	1.14	3.8	173	19.82	0.62	3.1	174	94.80	4.30	4.5
Abbott Architect i System	142	29.02	1.25	4.3	142	19.24	0.79	4.1	141	92.73	5.19	5.6
Beckman Access/2	68	23.58	1.36	5.8	68	16.00	0.86	5.4	68	70.04	4.37	6.2
Beckman UniCel Dxl	277	22.65	1.29	5.7	276	15.29	0.82	5.3	276	66.93	4.49	6.7
Roche cobas e411/Elecsys	65	36.62	1.73	4.7	66	23.88	1.28	5.4	66	118.96	6.25	5.3
Roche cobas e600 series/E170	215	34.69	1.21	3.5	216	22.52	0.87	3.8	214	113.50	3.71	3.3
Roche cobas e801/e402	240	33.92	1.32	3.9	241	22.09	0.93	4.2	241	110.51	8.39	7.6
Siemens ADVIA Centaur XP/XPT	118	20.05	0.92	4.6	118	13.35	0.55	4.1	119	65.48	4.90	7.5
Siemens Atellica IM	183	19.68	0.88	4.5	181	13.12	0.52	4.0	183	63.48	3.75	5.9
Siemens Dimension Vista	64	26.81	0.56	2.1	64	17.10	0.43	2.5	63	90.47	2.27	2.5
Siemens Immulite 2000/XPi	17	29.01	1.66	5.7	17	18.92	0.96	5.1	17	93.08	6.08	6.5
Snibe Maglumi series	14	33.16	2.46	7.4	14	21.19	1.50	7.1	14	97.41	11.23	11.5
Vitros 3600, 5600, ECI/ECIQ, XT 7600	100	22.72	1.01	4.4	102	15.69	0.77	4.9	101	69.05	2.96	4.3
Vitros 36/56/XT76,ECI/ECIQ Prol2	17	22.19	0.83	3.7	17	15.03	0.73	4.9	16	70.04	3.29	4.7



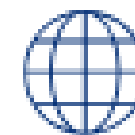
Global Laboratory Standards for a Healthier World

CLSI brings together the worldwide laboratory community to advance a common cause.



Centers for Disease Control and Prevention

CDC 24/7: Saving Lives, Protecting People™



ifcc
International Federation
of Clinical Chemistry
and Laboratory Medicine



**World Health
Organization**



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EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

We're ISO, the
Organization

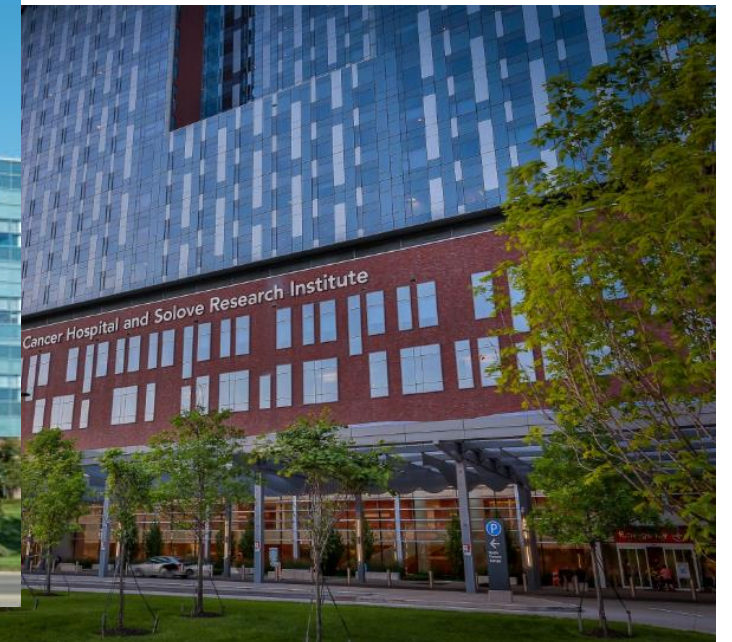


Harmonizing Hemoglobin A_{1c} Testing

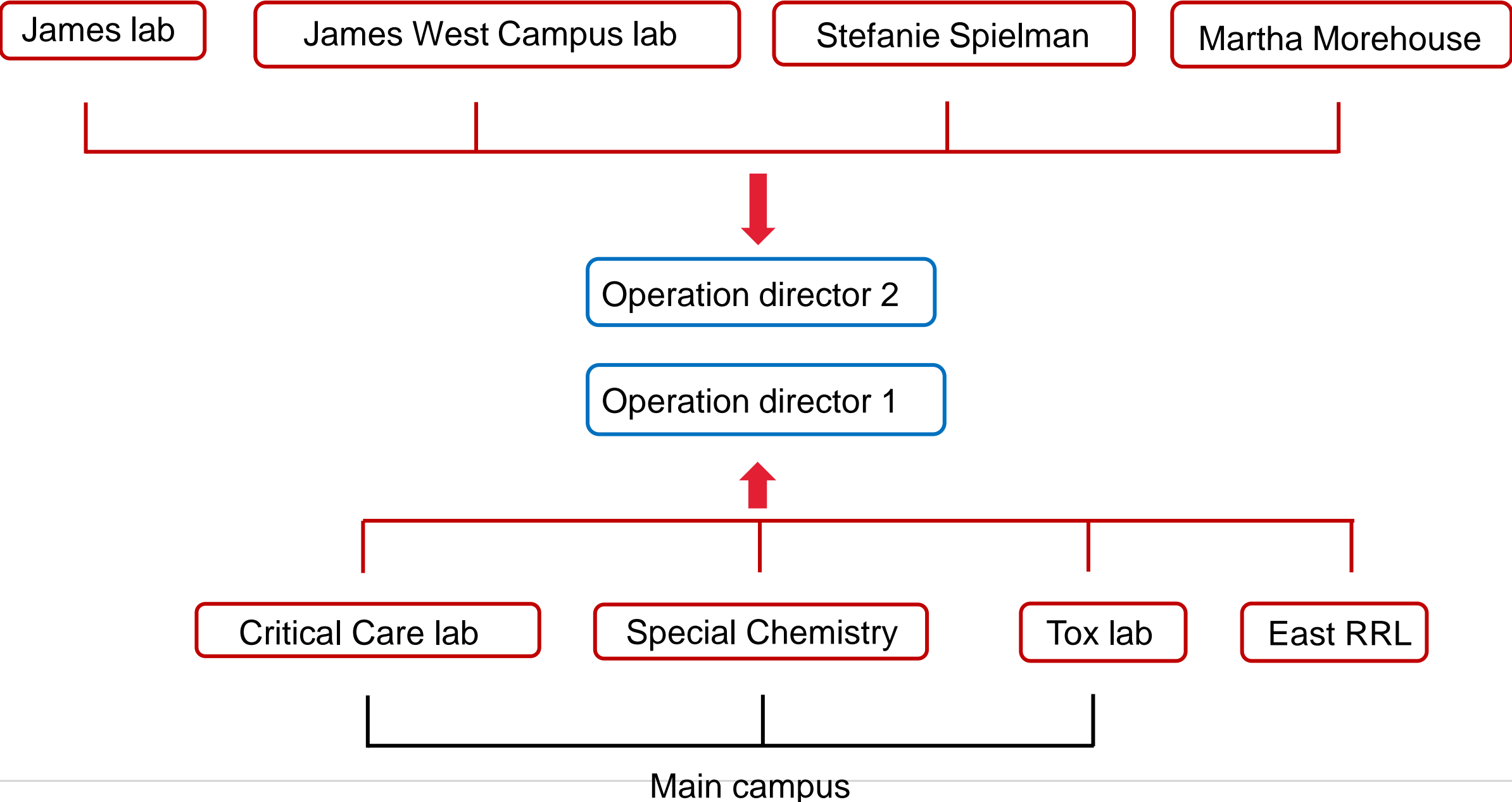
A better A1C test means better diabetes care



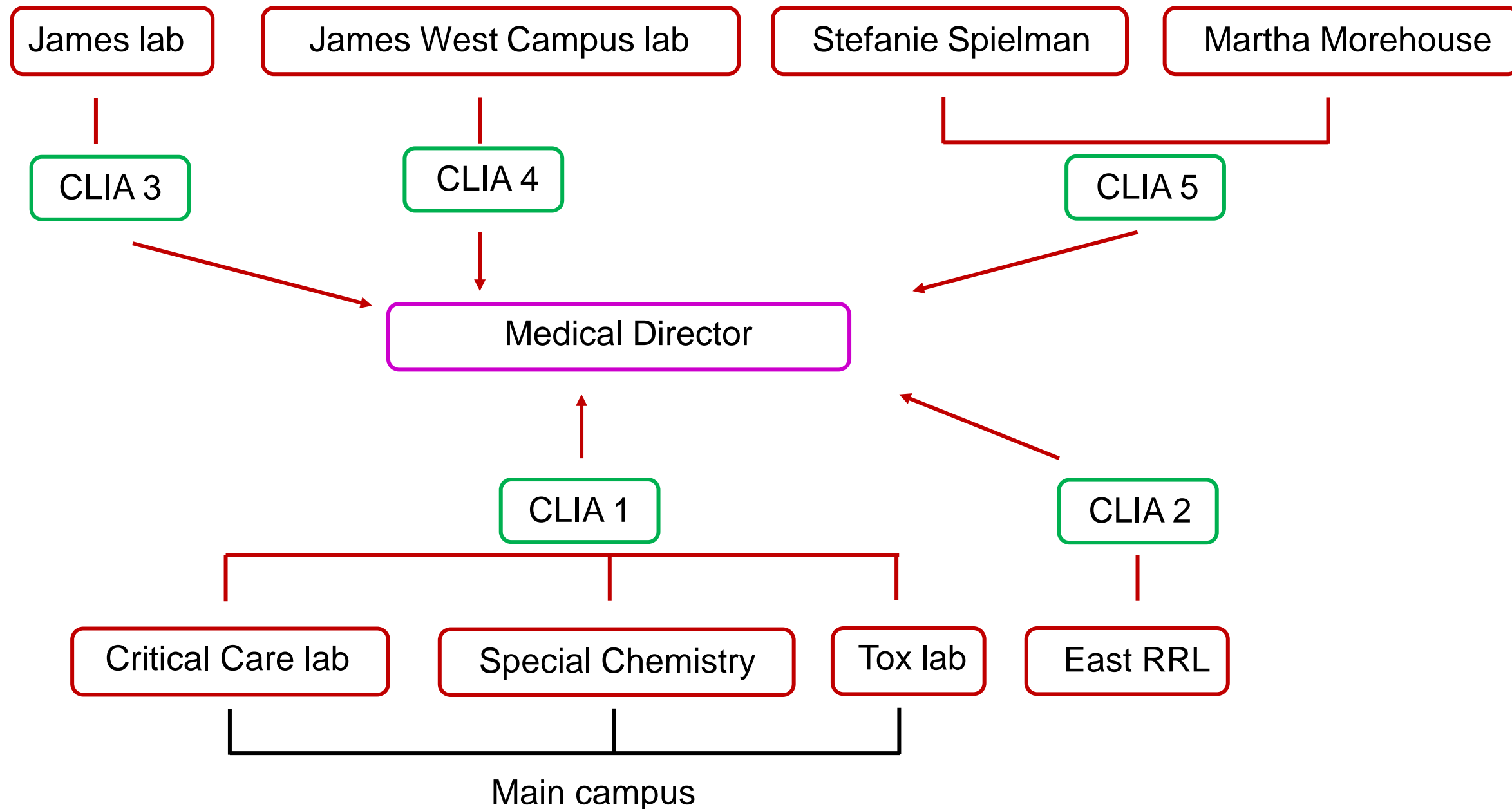
The Ohio State Wexner Medical Center-Clinical Laboratories



Structure of Our Clinical Chemistry Laboratory



Structure of Our Clinical Chemistry Laboratory



Standardization

Pre-analytical
phase

Analytical
phase

Post-analytical
phase

Quality
improvement

Management

Policies
and procedures



Analytical phase

Methodology/instrumentation

Quality control system (calibration, quality control, periodic correlation study between all labs, proficiency testing, etc.)

Test harmonization



Methodology/instrumentation



Critical Care Lab

James Lab, James WC Lab

Toxicology Lab

East hospital

**Stefanie Spielman Comprehensive Breast
Center**

The James Martha Morehouse Outpatient Care



Methodology/instrumentation



Critical Care Lab
Special Chemistry Lab
James Lab
James WC Lab
East hospital



Analytical phase

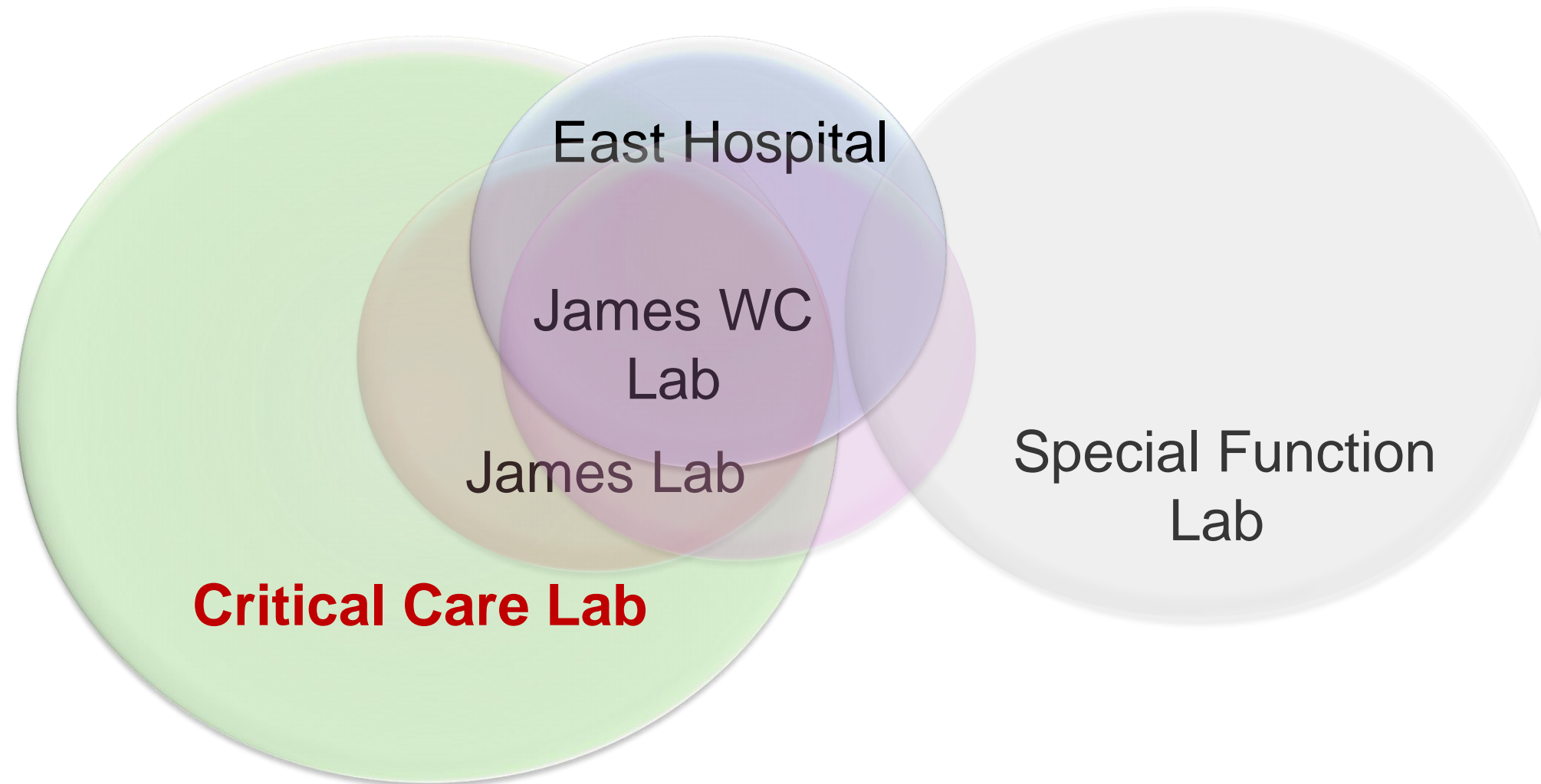
Methodology/instrumentation

Quality control system (calibration, quality control, periodic correlation study between all labs, proficiency testing, etc.)

Test harmonization



Periodic correlation study between all labs – Immunochemistry



Analytical phase

Methodology/instrumentation

Quality control system (calibration, quality control, periodic correlation study between all labs, proficiency testing, etc.)

Test harmonization



Guidelines

Canadian Society of Clinical Chemists Harmonized Clinical Laboratory Lipid Reporting Recommendations on the Basis of the 2021 Canadian Cardiovascular Society Lipid



Harmonizing Hemoglobin A1c Testing

A better Clinical Chemistry 64:4
645-655 (2018)

Special Report

International Federation of CI Standardization of HbA1c

Clinical Laboratory Practice Recommendations for the Use of Cardiac Troponin in Acute Coronary Syndrome: Expert Opinion from the Academy of the American Association for Clinical Chemistry and the Task Force on Clinical Applications of Cardiac Bio-Markers of the International Federation of Clinical Chemistry and Laboratory Medicine

Alan H.B. Wu,^{1*} Robert H. Christenson,² Dina N. Greene,³ Allan S. Jaffe,⁴ Peter A. Kavsak,⁵
Jordi Ordonez-Llanos,⁶ and Fred S. Apple⁷





List of CDC CSP Reference Measurements

- [Total cholesterol](#)
- [Total glycerides](#)
- [HDL-cholesterol](#)
- [LDL-cholesterol](#)
- [Testosterone*](#)
- [Estradiol*](#)
- [25-OH-vitamin D2*](#)
- [25-OH-vitamin D3*](#)
- [Free thyroxine*](#)
- [Glucose*](#)

List of CDC CSP Monitoring Programs

[Accuracy-based Monitoring Programs \(AMP\) for Testosterone](#)

[Lipids Standardization Program](#)

List of CDC CSP Certification Programs

- [Cardiovascular Disease Biomarker Standardization Program](#)
- [Hormone Standardization Program for Estradiol and Testosterone](#)
- [Vitamin D Standardization Certification Program](#)



Pre-analytical phase

Test menu/utilization

Test ordering

Patient preparation

Sample collection, handling and transportation

Interferences, e.g. hemolysis, icterus or lipids



Test menu



THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

The Ohio State Wexner Medical Center Labs Test Catalog

powered by Mayo Clinic Laboratories

Help

Browse by Name

A	B	C	D	E	F
G	H	I	J	K	L
M	N	O	P	Q	R
S	T	U	V	W	X
Y	Z	#			

Search

Search

Offering the most comprehensive laboratory testing services in Central Ohio, the Clinical and Reference Laboratories at Ohio State's Wexner Medical Center is your partner in delivering high quality patient care. As part of one of the nation's top-ranked medical center, we are at the forefront of developing new technologies and services.



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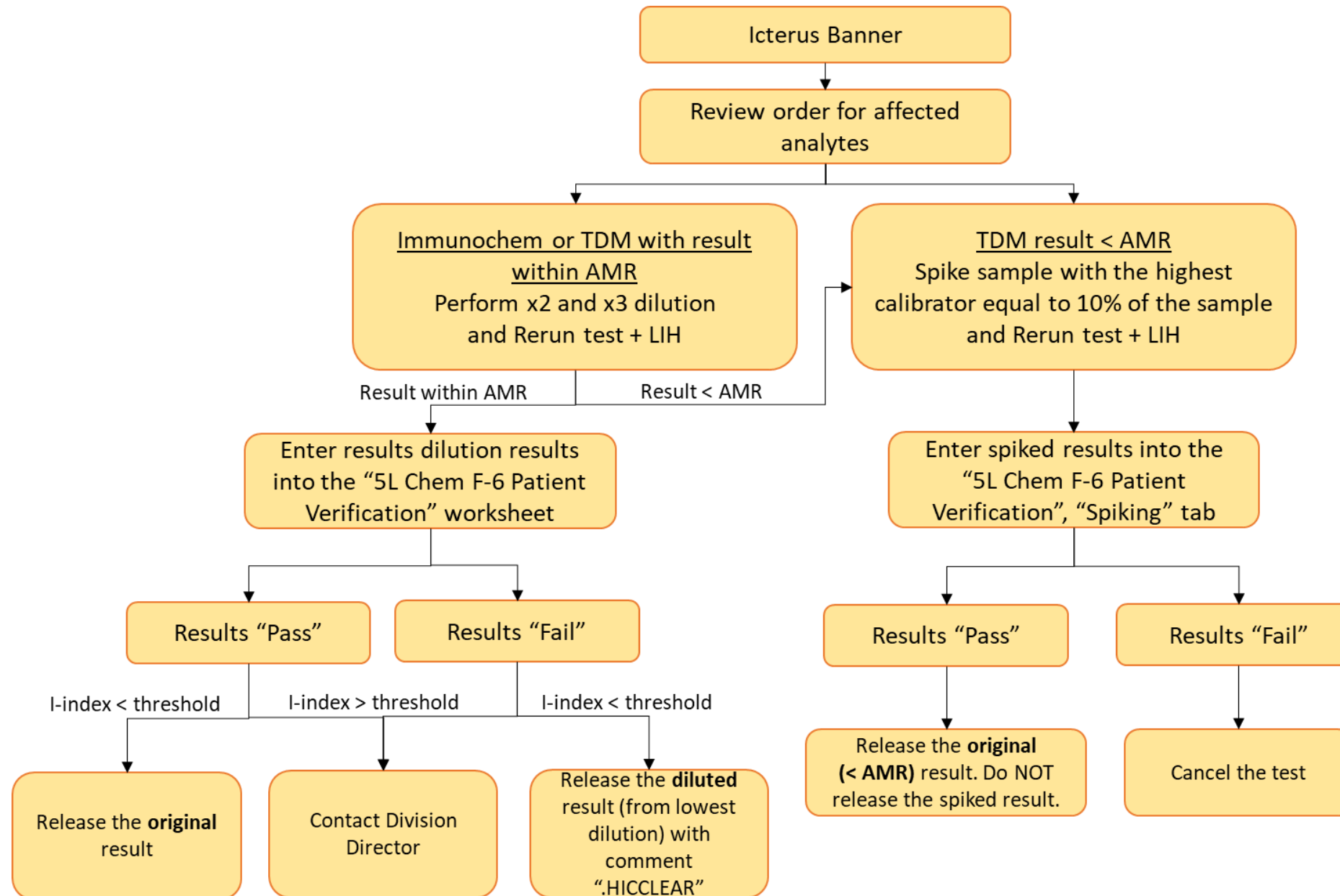


Interferences, e.g. hemolysis, icterus or lipids

Analyte	I-Index Threshold	Action
Lithium	4+	Algorithm
Methotrexate	3+	Cancel
Phenobarbital	4+	Algorithm
Phenytoin	2+	Cancel
Prealbumin	4+	Algorithm
RF	4+	Algorithm
Salicylate	3+	Cancel
Theophylline	4+	Algorithm
Tobramycin	4+	Algorithm
Vancomycin	4+	Algorithm



Interferences, e.g. hemolysis, icterus or lipids



Post-analytical phase

Laboratory information system (LIS) -Results reporting (units, AMR, CRR, Reference intervals, Critical value notification, etc)

Middleware rules for auto filling results, and result flags management

Results interpretation

Turnaround time



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Approaches to bringing standardizations in one health system



Approaches to bringing standardizations in one health system

- ✓ Common reporting structure
- ✓ Leadership
- ✓ The same financial process
- ✓ The same IT systems
- ✓ The same testing methods



Approaches to bringing standardizations in one health system

- ✓ Published guidelines
- ✓ Evidence-based practices
- ✓ Document management
- ✓ A culture of “our laboratory system,” not “my individual laboratory site.”



The Benefits

- ✓ Better quality
- ✓ More efficiency
- ✓ Optimizing workflow
- ✓ Improve outcomes
- ✓ Better satisfaction



The Benefits

- ✓ Inventory management
- ✓ Supply chain
- ✓ Cost control
- ✓ Training programs
- ✓ Test interpretation



Challenges of Standardization

- ✓ If no common reporting structure
- ✓ If separate leadership
- ✓ If separate financial process
- ✓ If separate IT systems
- ✓ If different testing methods (different AMR, CRR, reference ranges, critical values, etc.)



Challenges of Standardization

- ✓ Standardization of procedure
- ✓ Test innovation



Acknowledgement

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- ✓ Sandra VanVranken and the entire compliance team
- ✓ All the other Laboratory Directors
- ✓ The OSU administration team
- ✓ All the OSU clinical laboratories





Thank you