MAYO CLINIC

Wisconsin Clinical Laboratory Network Webinar

Challenges of Reimbursement for Molecular Infectious Disease Syndromic Panel Testing

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Disclosures

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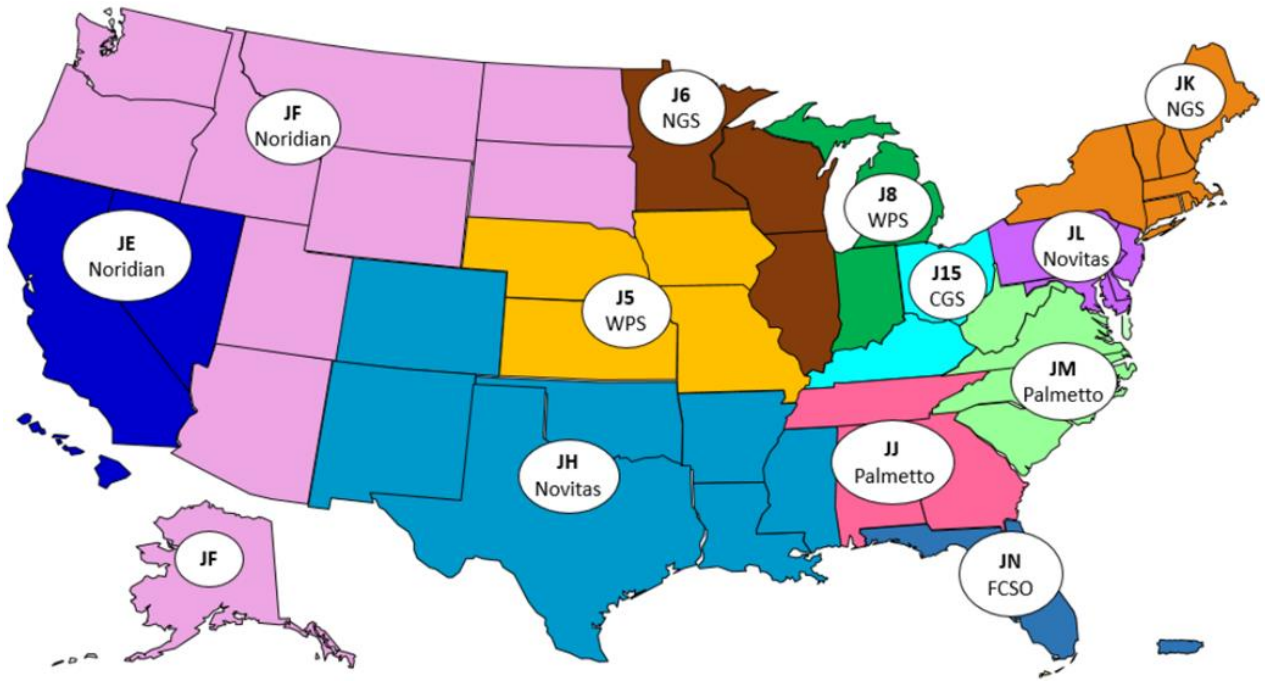
Learning Objectives

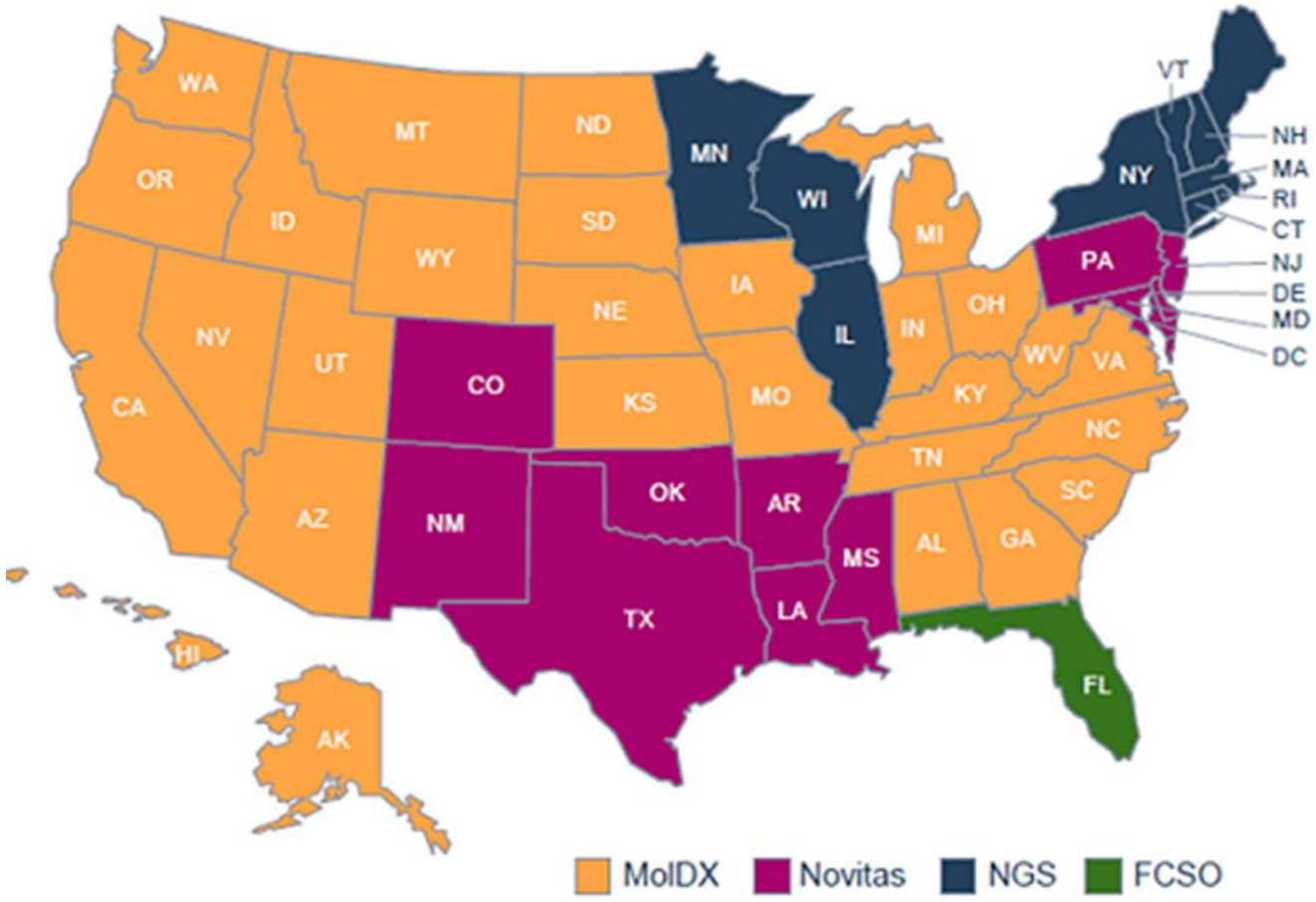
1. Describe the latest MolDx reimbursement criteria and rules on molecular syndromic panels for infectious disease pathogen identification testing.
2. Explain the implications of the new reimbursement rules on clinicians' use of these diagnostic panel tests.
3. Discuss potential strategies and approaches of diagnostic stewardship to enable medically necessary use of these panel tests and meet reimbursement criteria.

Medicare Administrative Contractors (MAC)

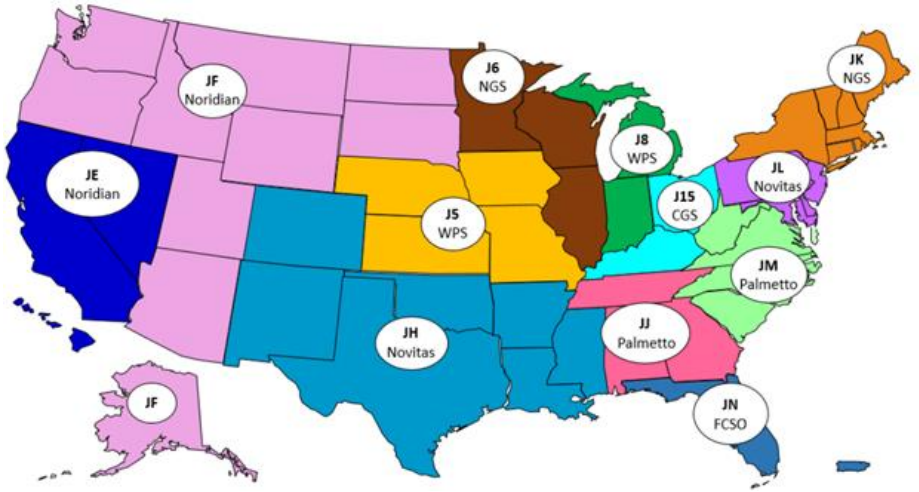


- MAC = Private health care insurers awarded by CMS to process Medicare Part A and Part B medical claims or durable medical equipment (DME) claims for Medicare Fee-For-Service (FFS) beneficiaries in various U.S. geographic areas.
- 7 current MAC: *CGS, FCSO, Palmetto GBA, NGS, Noridian, Novitas, WPS*

Medicare Administrative Contractors (MAC) and Local Coverage Determination (LCD) for MolDx



- MolDX Program was developed in 2011 to identify and establish coverage reimbursement for molecular diagnostic tests.
- MolDx currently provides uniform policies for 28 states, across 4 MAC.



Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing

LCD L38988, effective June 9, 2022

- Limited coverage for **outpatient** testing with molecular syndromic panels for infectious disease pathogen identification testing.
- Does NOT address coverage for the inpatient setting.
- Panel = A test that detects >1 pathogen
- Syndromic panel = simultaneously detects multiple different pathogens associated with similar and overlapping clinical symptoms and signs.
  - Targeted panels: ≤ 5 pathogens
  - Expanded panels: ≥ 6 pathogens
- Not a coverage policy for metagenomic NGS, mass spectrometry, or fluorescence in situ hybridization (FISH).

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38988&ver=11&bc=0

Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing in *Outpatients*

ID molecular syndromic panel test *(≥ 6 pathogens)*	Ordered by or in consultation with these clinician specialists		Ordered by all licensed clinicians
	Immunocompetent	***Immunocompromized***	***All patients***
Respiratory / Pneumonia	*Those with known underlying respiratory pathology:* **Infect Dis, Pulmonary** CPT 87632 (6-11), 87633 (12-25), 87801 (multiple)	**Infect Dis, Pulmonology, Oncology, Transplant** CPT 87632 (6-11), 87633 (12-25), 87801 (multiple)	
Gastrointestinal	*Those with known underlying GI pathology:* **Infect Dis, GI** CPT 87506 (6-11), 87507 (12-25)	**Infect Dis, GI, Oncology, Transplant** CPT 87506 (6-11), 87507 (12-25)	Diarrheal illness lasting >7 days + NOT on laxatives within 24 hrs before testing

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38988&ver=11&bc=0

Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing in *Outpatients*

ID molecular syndromic panel test *(≥ 6 pathogens)*	Ordered by or in consultation with these clinician specialists		Ordered by all licensed clinicians
	Non-ICH	***ICH***	***All patients***
Meningoencephalitis			CSF collected only by lumbar puncture, not from indwelling medical devices (shunts, reservoir). CPT 87483 (12-25)
Bloodstream infection *(Blood or blood culture media)*			Clinical sepsis + organism(s) seen on Gram stain of blood culture + managed in ED + antimicrobial stewardship team service CPT 87154 (≥6)

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38988&ver=11&bc=0

Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing in *Outpatients*

ID molecular syndromic panel test *(≥ 6 pathogens)*	Ordered by or in consultation with these clinician specialists		Ordered by all licensed clinicians
	Non-ICH	***ICH***	***All patients***
UTI *(Urine)*	Evaluated by **urology** or **gynecology** specialists CPT 87801 (multiple)		Symptomatic, at high risk for UTI complications (eg, elderly, recurrent UTI hx, underlying urinary tract pathology) CPT 87801 (multiple)
Infectious vaginitis *(High risk if asymptomatic)*			Panel must have ≥2 of the following: *G. vaginalis*, other BV-associated bacteria (BVAB) (such as *Atopobium vaginae* and/or *Megasphaera* types), *Trichomonas vaginalis*, and *Candida* species. CPT 81513 (bacterial), 81514 (bacteria + *Candida*), 87800 (direct), 87801 (amplified)

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38988&ver=11&bc=0

Approaches to meet 2022 MolDx Reimbursement Eligibility Criteria

1. Diagnostic stewardship program
2. Automated “pop-up” EHR lab test ordering reminder on pre-requisites (clinical decision support / dynamic test ordering tests)
3. Programing of lab test billing software to avoid sending CPT codes of “overlapping” molecular ID syndromic tests to insurance payers

COVID-19/FLU/RSV Testing (IP)

COVID-19 Results

** No results found for the last 4500 hours. **

COVID19 Testing Guidance for the following Approved Services/Indications:

Category	Expectation/Turnaround	Potential Services/Indications
Pre-Procedure	See detail in panel instruction	Same Day Procedure, Next Day Procedure or Procedure within 3 days
Rapid Ô	Results will be available as rapidly as possible.	Symptomatic Inpatient Diagnostic Testing, Anticipated Delivery within 6 hours, Urgent OB Procedures,Gift of Life/Organ Transplant, Symptomatic Nursery/Pediatric
Urgent ÔÔ	Results will have a quick turnaround and be within the same day	Inpatient Direct Admit, Anticipated Delivery greater than 6 hours, Asymptomatic Nursery/Pediatric, Transfer to Another Facility, Psychiatry Admission Protocol

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○ Pre-Procedure Testing

◉ Rapid Testing

Place isolation order within this panel for symptomatic patients

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☐ Symptomatic Diagnostic Testing - COVID-19+FLU A/B+RSV

☐ OB Delivery Rapid/OB Procedure - COVID-19

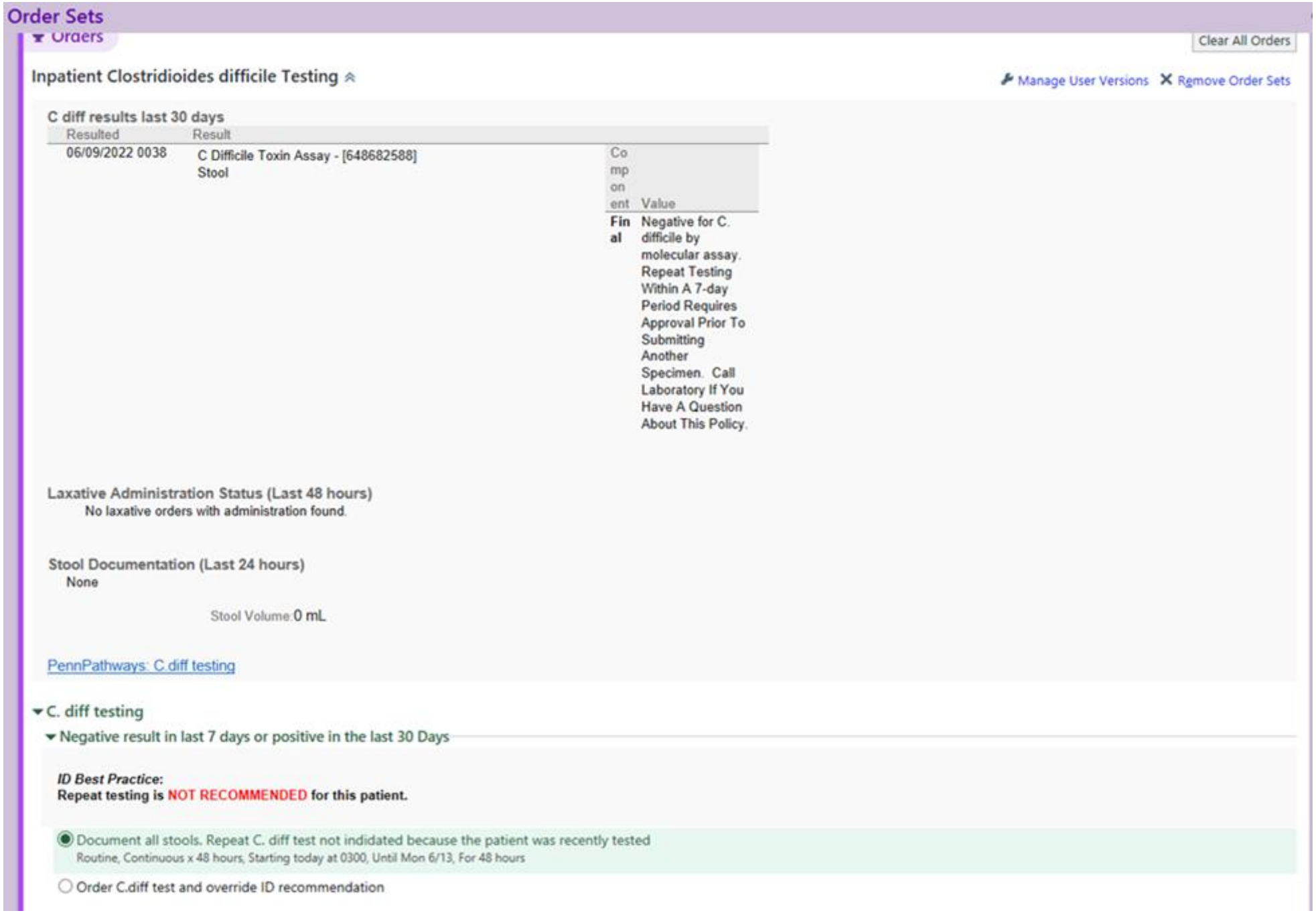
☐ Gift of life/Organ Transplant - COVID-19

☐ Symptomatic Nursery/Pediatric - COVID-19+FLU A/B+RSV

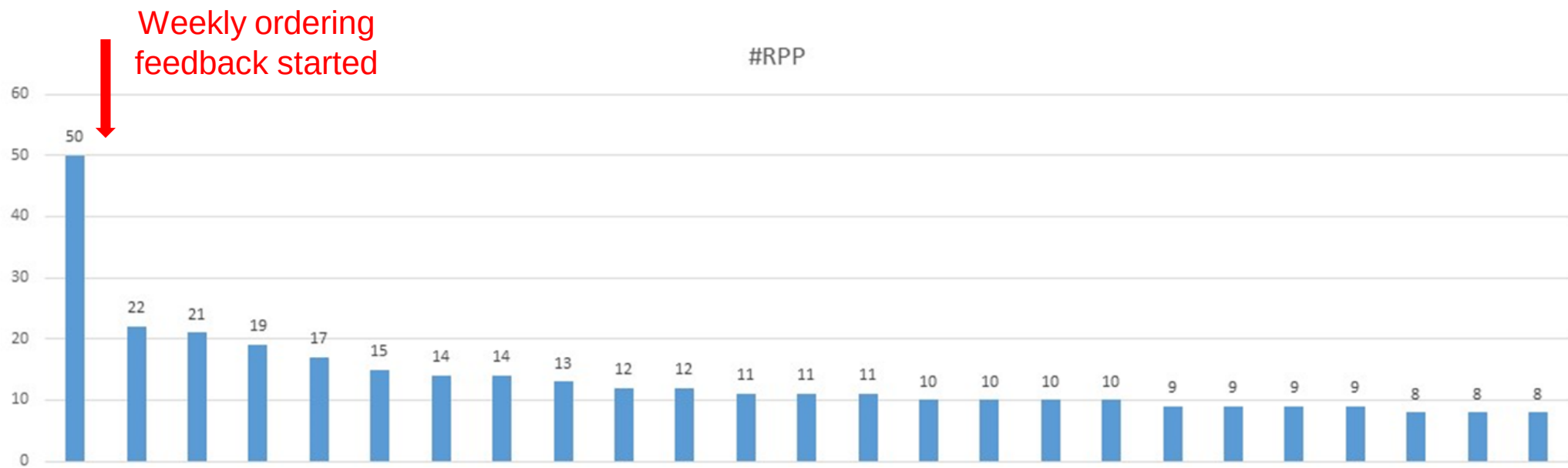
☐ Other Indication - COVID-19

☐ Special Respiratory Precautions for Symptomatic Patient

○ Urgent Testing



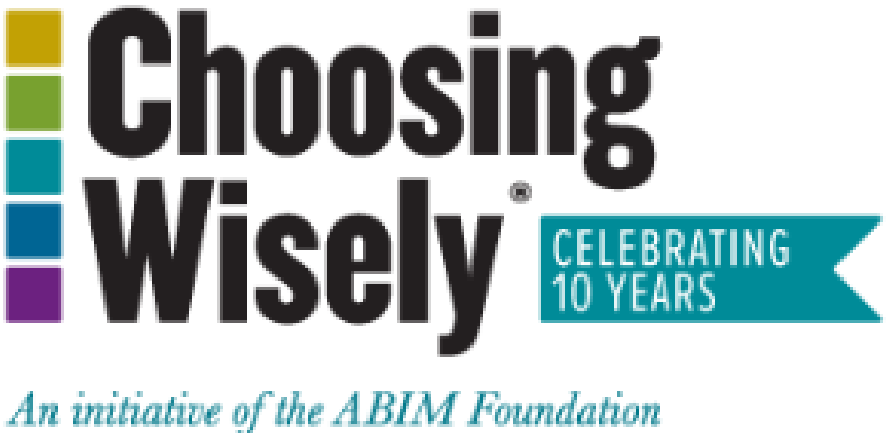
RPP orders by ordering physician



Resources

- Diagnostic stewardship committee
- *Choosing Wisely Campaign*
- Clinical practice guidelines
- American Thoracic Society (ATS), Infectious Disease Society of America (IDSA), ASM recommend some multiplex testing only for certain higher-risk in-patients

Choosing Wisely Campaign



The mission of *Choosing Wisely* is to promote conversations between clinicians and patients by helping patients choose care that is:

- **Supported by evidence**
- **Not duplicative of other tests or procedures already received**
- **Free from harm**
- **Truly necessary**

Complete lists of recommendations by society can be found by clicking the society name or via individual recommendation pages.

Your search returned 5 results

Society	Recommendation
American Society for Microbiology	Do not order urine cultures unless patients have symptoms consistent with urinary tract infection (UTI).
American Society for Microbiology	Do not order a Lyme immunoblot without a positive Lyme Enzyme immunoassay (EIA) screening test.
American Society for Microbiology	Do not order Lyme serology on patients with a primary erythema migrans lesion.
American Society for Microbiology	Do not routinely test >1 stool specimen per week for Clostridioides difficile by Nucleic-acid Amplification Test (NAAT).
American Society for Microbiology	Do not request routinely extended incubation of blood cultures in suspected endocarditis.

Search Recommendations

American Society for Microbiology

- filter by -

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SEARCH

Clear Filters

Continue the Conversation

Summary

- Diagnostic stewardship is an emerging field that will be helpful to guide judicious use of diagnostic laboratory tests
- Limited evidence-based guidelines on effective stewardship interventions for multiplex syndromic panels
- Get creative and share our experiences

QUESTIONS & ANSWERS