

# Regulatory Program Updates and Mandatory Guidelines

## Center for Substance Abuse Prevention

### Drug Testing Advisory Board

Ron Flegel, BSMT (ASCP), MS

DTAB Chair

Division of Workplace Programs

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

June 4, 2024  
Open Session - Public



**SAMHSA**  
Substance Abuse and Mental Health  
Services Administration

# Division of Workplace Programs

- Director: Ron Flegel, B.S., MT(ASCP), M.S.
- Contracting Officer Representative: Eugene D. Hayes, Ph.D., M.B.A.
- Public Health Advisor: Anastasia Flanagan
- Senior Toxicology Policy Advisor: Lisa S. Davis, M.S.
- Senior Policy Analyst: Coleen Sanderson
- Policy Oversight Lead: Hyden Shen, J.D.
- Social Science Analyst: Brijet Burton
- Senior Pharmacist: LCDR Joshua Hunt, PharmD, MPH (USPHS)
- Senior Scientist Policy Advisor: CAPT Sean Belouin, Pharm.D.
- Program Assistant: Christie Lamb

# Drug Testing Advisory Board Members

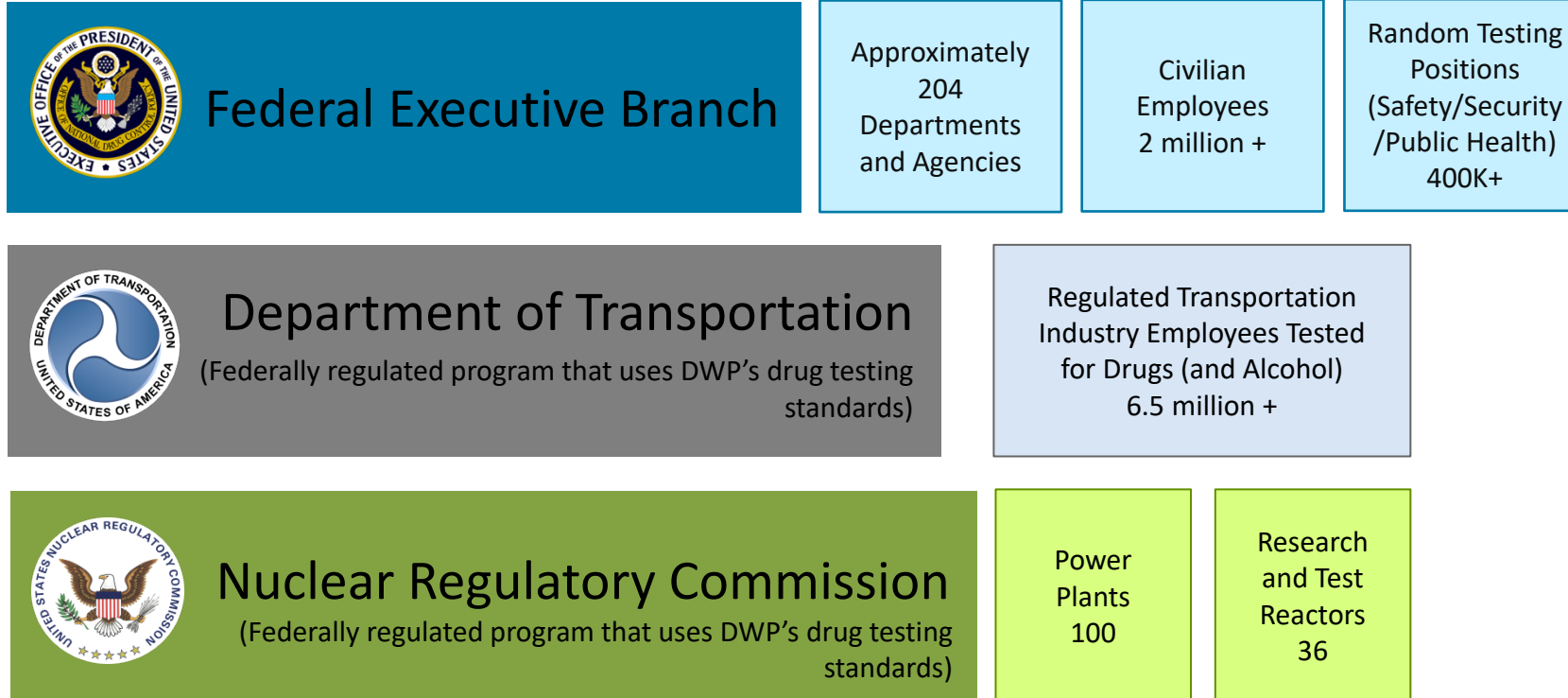
- David Engelhart, Ph.D.
- Elizabeth Stuyt, MD
- David Roberts, Ph. D.
- E. Lindsey Everson, J.D.
- Dawn Hahn
- Bryan Ruggery
- Michael Grommes
- Carl Christensen, MD
- Samantha Tolliver, Ph.D
- Bonnie Droter

# DWP Objectives and Goals

- **Overall Goal:** *“SAMHSA is continually assessing the science and technology used in drug detection to advance national drug policy that is based on the latest scientific findings.”*
- **Goal:** Continue to move the Federal Drug Testing Program forward and current state of the DFWP, examine the issues affecting the program, outline responses to these critical issues and look at initiatives to address the unanswered questions.
- **Future:** *Identify key policy and technical issues as well as the existing challenges both current and future for Implementation of the Mandatory Guidelines using oral fluid and/or hair, and enhancements to the Federal Drug Testing Program.*

# Drug-Free Workplace Program Impact

5



DFWP Program Impacts 14 million+ employees



# Division of Workplace Programs Legislative Authority and Main Roles



## Science Federal Forensic Drug Testing

### DWP's Science Responsibilities:

1. **Mandatory Guidelines for Federal Drug Testing:** Scientific & Technical Guidelines
  2. **National Laboratory Certification Program (NLCP):** Certifies labs for federal (and federally-regulated) forensic drug testing
  3. **Drug Testing Advisory Board (DTAB):** National Advisory Council of experts on federal and federally regulated drug testing activities
  4. **Medical Review Officer (MRO)\* Training:**
    - Establishes MRO certification standards
    - Certifies MRO training entities
- \* MROs interpret drug testing results on drug use.

### Programs Outcomes:

- National drug testing standards
- Alternative specimen testing (Urine, Oral Fluid, Hair)
- HHS Certified Laboratories
- DTAB Recommendations for the Assistant Secretary
- National MRO certification standards

## Policy Drug Free Workplace Program

### DWP's Policy Responsibilities:

1. **Technical Assistance to all Federal Agencies:** Assistance and review of agency plans on implementing the DFWP
2. **Plan Certification:** Certify federal agency DFWP plans, transmit agency plans/reports to Congress. Agency plans establish agency policy and procedures.
3. **Executive Committee:** Interagency Coordinating Group Executive Committee (ICGEC) establishes policy and approves federal Testing Designated Positions (TDP's) of safety-sensitive positions
4. **Policies/Legislation:** Evaluating impact of policies and legislation on the DFWP, i.e., Farm bill, state marijuana laws, decriminalization

### Program Outcomes:

- Certified DFWP plans for all federal agencies
- DFWP policy and procedures for all federal agencies
- Policy Discussions with ONDCP
- Policy and Legislative Impact on the DFWP

## Science and Policy Emerging Issues Group

### DWP's Emerging Issues Responsibilities:

1. **Monitor domestic drug prevalence data:** Utilize NFLIS (DEA), NSDUH (SAMHSA), MTF (NIDA), CDC overdose data and MMWRs, and Quest Drug Testing Information to identify new trends and emerging threats of Novel Psychoactive Substances or new adulterants in the illicit supply chain which pose a threat to workplace safety and public health.
  - Monitor international drug misuse trends through WHO, United Nations, DEA, ONDCP, NIDA, and State Department interactions.
2. **Solicit and review drug testing data:** Applicable federal partners include (DoD, DOT, NRC, DEA), HHS-Certified laboratories, research scientists, manufacturers of collection devices/immunoassay kits.
3. **Supports Scientific Studies:** Scientific and technical review of the DFWP.
4. DTAB review for drug analyte addition or removal

### Program Outcomes:

- Recommend DFWP analyte table changes (Science)
- Policy Discussions with ONDCP (Policy)
- Policy and Legislation Impact on the DFWP (Policy)
- Recommendations for the addition or removal of an analyte to the Assistant Secretary (Science)

# Current Drug-Free Workplace Program

Updated: May 2024

**Total number of Executive Branch agencies thought to be subject to EO 12564 .....202**

*(Sources: Federal Register (FR), Administrative Conference of the United States (ACUS), USA.gov 2020)*

**Total number of Executive Branch agencies with certified plans .....131**

*(Source: The CDM Group)*

**Total number of Executive Branch agencies identified without certified plan and without evidence that they are not required to comply with EO 12564.....71\***

*(Source: The CDM Group)*

*\*Further research/contact is needed to establish status for many of these*

# Mandatory Guidelines Update

## Urine

CURRENT Mandatory Guidelines for Federal Workplace Drug Testing using Urine effective February 1, 2024.

[2023-21734.pdf \(govinfo.gov\)](#)

## Oral Fluid

CURRENT Mandatory Guidelines for Federal Workplace Drug Testing using Oral Fluid (OFMG) effective October 10, 2023.

[2023-21735.pdf \(govinfo.gov\)](#)

## Hair

PROPOSED Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair in September 10, 2020 Federal Register for public comment.

[2020-16432.pdf \(govinfo.gov\)](#)

*A revised proposal is pending OMB Review*



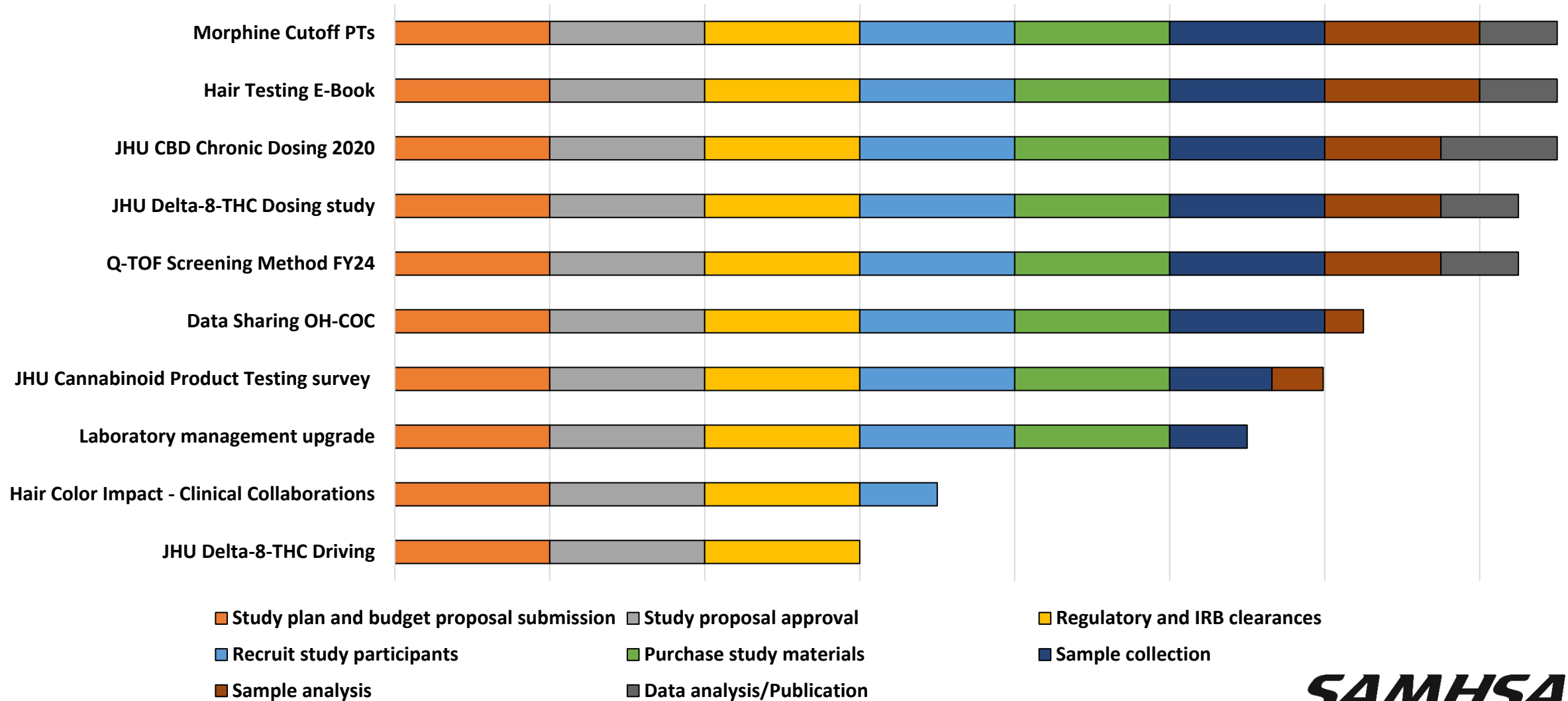
# Mandatory Guideline Routing Process



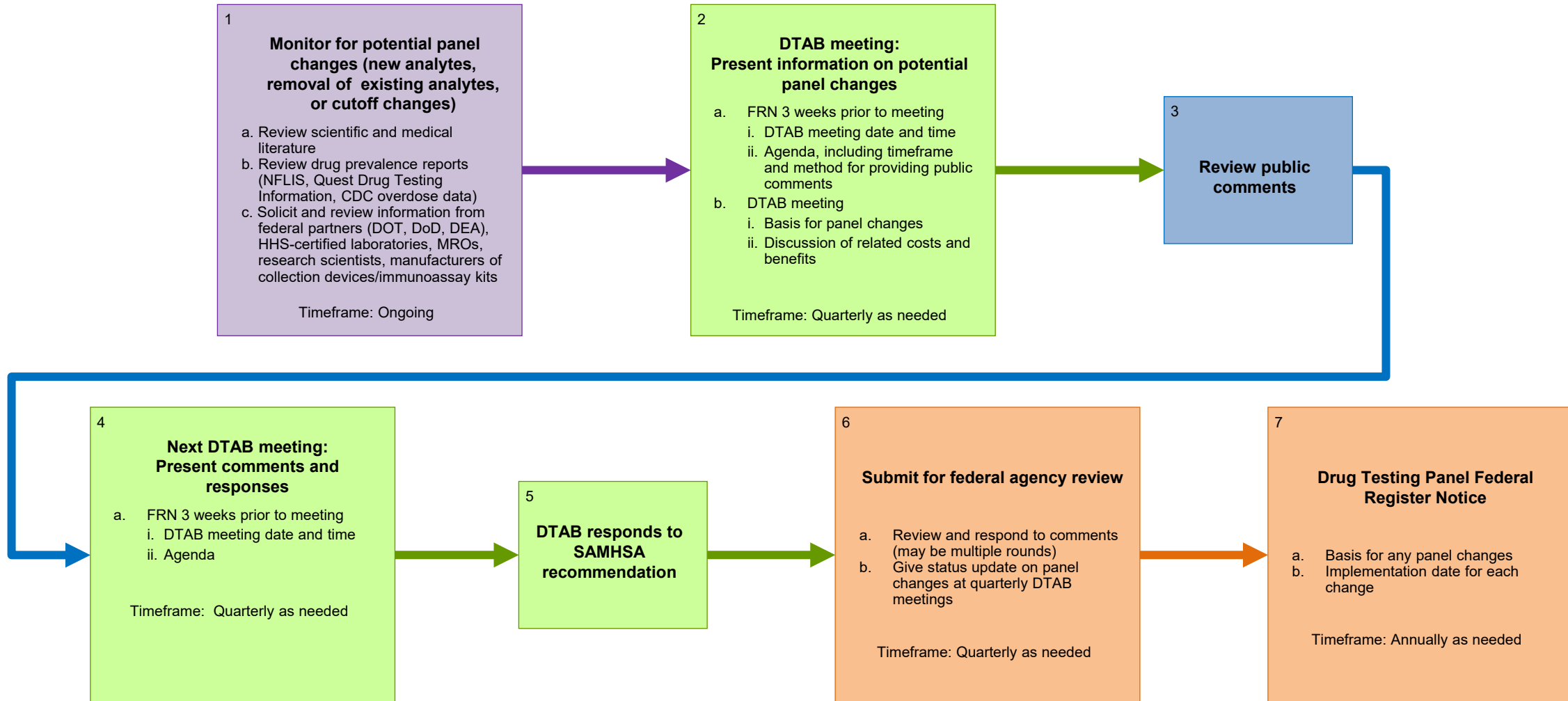
# Hair Mandatory Guidelines – Status

- SAMHSA public comment review:
  - Organized public comments by subject (over 700 individual comments from 213 commenters)
  - Reviewed all comments, submitted information, and scientific studies referenced by commenters – prepared draft HMG
- DTAB review
  - March 2021: summarized public comments presented for DTAB discussion
  - June 2021: members reviewed the draft HMG and provided input
- Hair Testing Laboratories – Listening Sessions
  - March – April 2022: SAMHSA listening sessions with 7 hair testing laboratories
  - Topics: proficiency testing requirements, quantitative agreement between labs, reporting criteria, future technical working groups
- Revised HMG has been submitted and is under OMB review

## Current NLCP Applied Studies (In-progress)



# Process for Drug Testing Panel Changes



# Proposed Testing Panel Changes and Request for Public Comment

- Nov. 17, 2023 Federal Register Notice for Dec. 5, 2023 DTAB meeting
- Public Comment period closed on January 4, 2024

Urine Analyte	Initial Test Cutoff	Confirmation Cutoff
Fentanyl	1 ng/mL	0.5 ng/mL
Norfentanyl	1 ng/mL	0.5 ng/mL

Oral Fluid Analyte	Initial Test Cutoff	Confirmation Cutoff
Fentanyl	1 ng/mL	0.5 ng/mL

Urine and Oral Fluid Analytes
Remove MDMA and MDA from both Urine and Oral Fluid Testing Panels

# Analyte Table Decisions

- Feb. 9, 2024 Federal Register Notice for Mar. 5, 2024 DTAB meeting

Urine Initial Test Analyte	Initial Test Cutoff	Confirmatory Test Analytes	Confirmation Cutoff
Fentanyl	1 ng/mL	Fentanyl Norfentanyl	1.0 ng/mL

- Include only Fentanyl (not Norfentanyl) as the sole initial test analyte for urine
- Raise the confirmatory test cutoffs for both Fentanyl and Norfentanyl in urine to 1.0 ng/mL

Oral Fluid Analyte	Initial Test Cutoff	Confirmatory Test Analytes	Confirmation Cutoff
Fentanyl	1 ng/mL	Fentanyl	1.0 ng/mL

- Raise the confirmatory test cutoff for Fentanyl in oral fluid to 1.0 ng/mL
- Remove MDMA and MDA from both urine and oral fluid drug testing panels

# Analyte Table Decisions

- June 4, 2024 DTAB meeting: Urine remains unchanged

Urine Initial Test Analyte	Initial Test Cutoff	Confirmatory Test Analytes	Confirmation Cutoff
Fentanyl	1 ng/mL	Fentanyl Norfentanyl	1.0 ng/mL

- Raise the initial test cutoff for Fentanyl in Oral Fluid to 4.0 ng/mL

Oral Fluid Analyte	Initial Test Cutoff	Confirmatory Test Analytes	Confirmation Cutoff
Fentanyl	4 ng/mL	Fentanyl	1.0 ng/mL

- Remove MDMA and MDA from both urine and oral fluid drug testing panels

# Oral Fluid Fentanyl Discussion for Cutoff Concentrations

- **Certified Laboratory Information**
  - 43% offer oral fluid testing to non-regulated workplace clients
  - 71% of these laboratories offer testing for fentanyl
  - Cutoffs
    - Initial test cutoffs ranged from 1 to 4 ng/mL for fentanyl
    - Confirmatory test cutoffs for fentanyl ranged from 0.5 to 1 ng/mL
- **Concentrations presented DTAB March 2024**
  - Literature: Median oral fluid fentanyl concentrations ranged from 1.15-8.1 ng/mL with cutoffs ranging from 0.1-1 ng/ml
  - CRL Workplace Oral Fluid median was 19.7 ng/mL; initial test cutoff was 3 ng/mL
- **Comments**
  - One commenter agreed with the proposed 1 ng/mL initial test cutoff for oral fluid
  - 10 commenters disagreed because of collection device buffer diluting the sample
    - Concerns about immunoassay QC requirements around the cutoff
    - Higher cutoffs supported by drug test results
  - One commenter suggested a cutoff between 2-4 ng/mL



# MRO Guidance Manual and Case Studies

- Updates based on the 2023 UrMG and OFMG.
  - Revisions to MRO verification process
  - Annual Authorized Drug Testing Panels, Authorized Biomarker Testing Panels, and Required Nomenclature for MRO Reports
  - MRO semi-annual reports to SAMHSA
- Updates based on MRO-relevant information from SAMHSA.
  - NLCP Notices
  - NLCP Manuals for Urine and Oral Fluid Laboratories
  - Guidance for Using the 2023 Federal CCF
- The Revised 2024 MRO Guidance Manual and Case Studies are posted on the SAMHSA website.

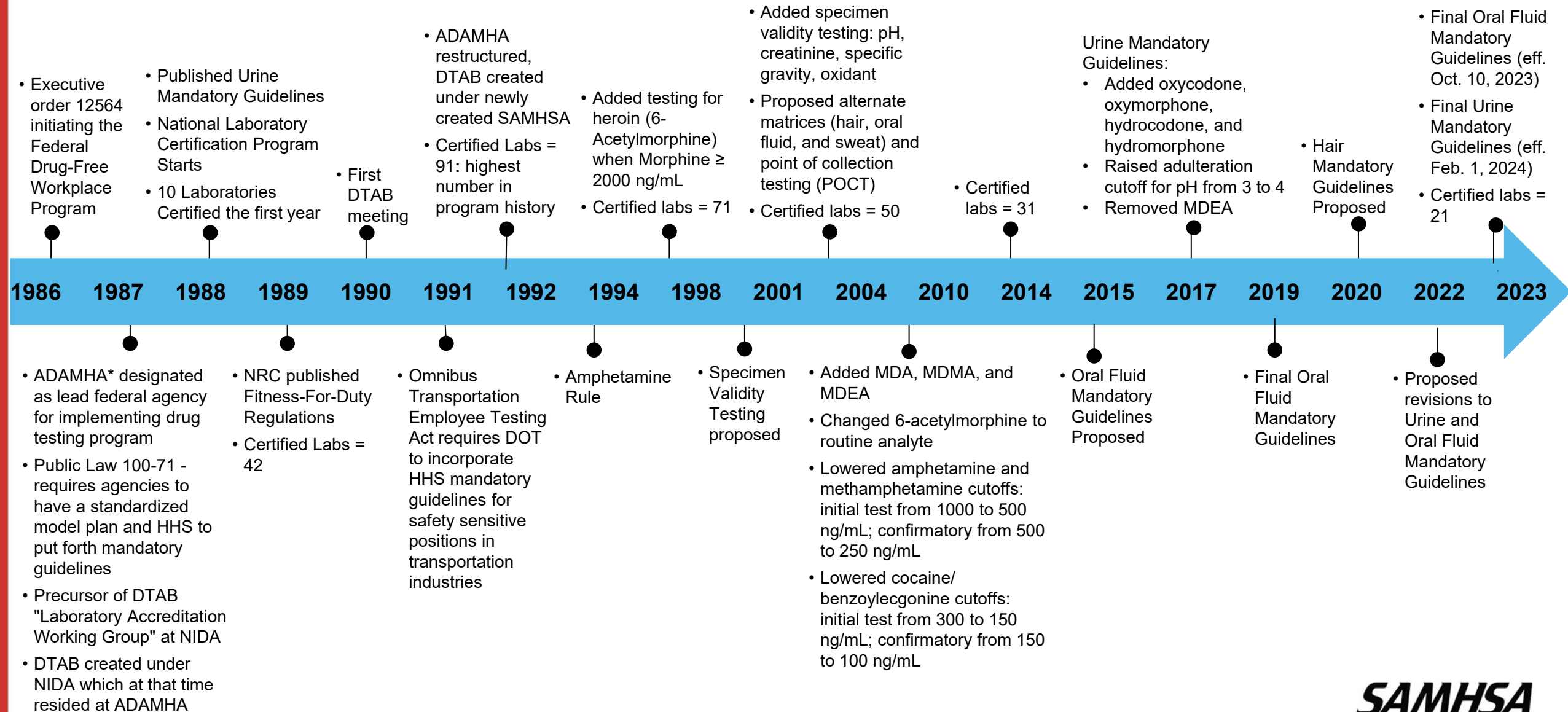
# Site Visit Objectives in the Federal Program

- New State-of-the-Art and Science for Oral Fluid
- Maintaining program integrity
  - Drug testing validity and reliability – Adulteration and Substitution
  - Workplace safety and security (i.e., safety-sensitive positions, fitness for duty)
- New issues, challenges, approaches and actions for DFWP
- Ongoing training needs for Laboratory Personnel
- Future studies and/or Request for Information
- Policy initiatives - ONDCP
- Future direction of the program and desired end state
- Resource needs

# Road Map and Action Plans

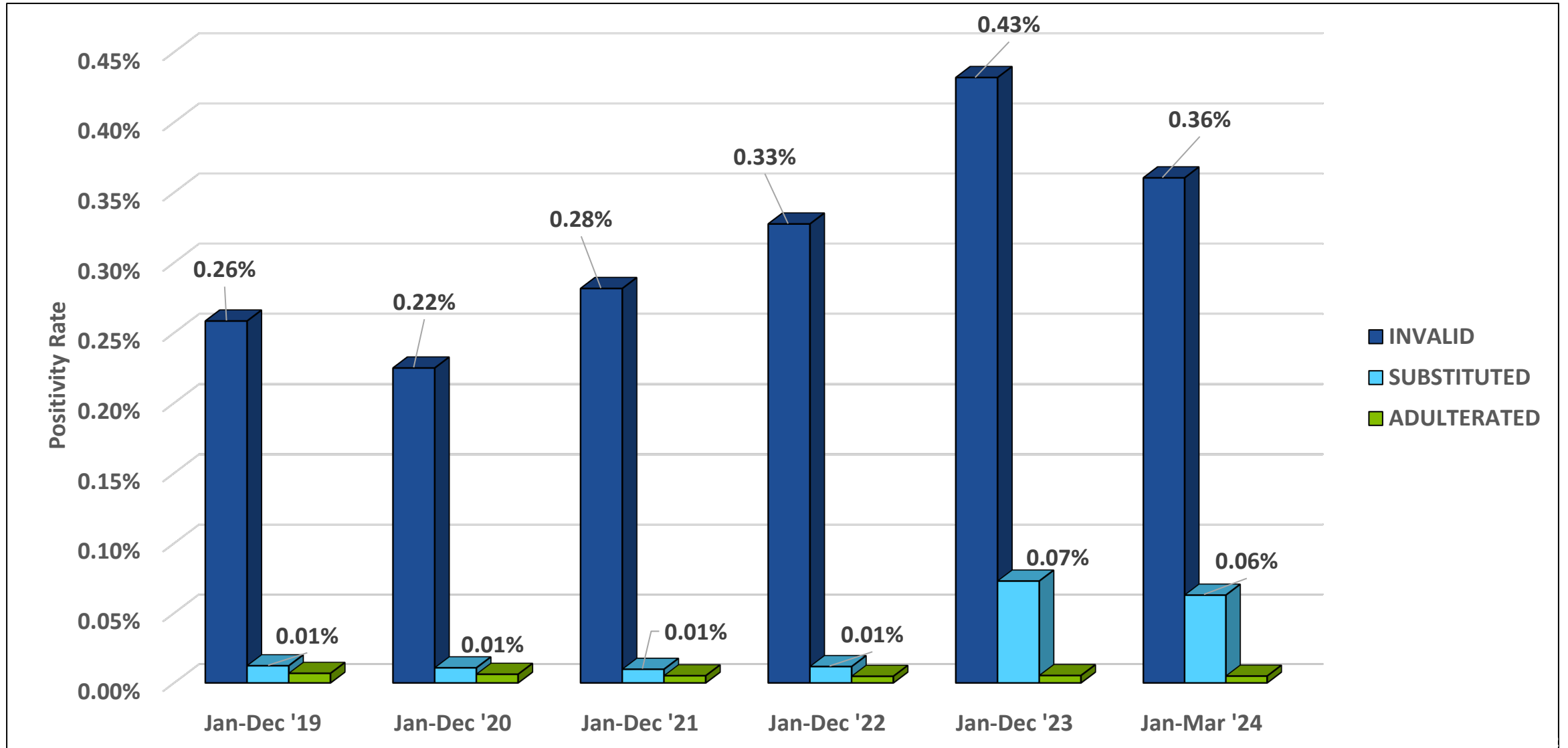
- Continue to work with FDA and Manufactures
- Continue to evaluate mechanisms for reducing time required to change the testing panel
- Develop and add new pulse testing (emerging drugs, specimen validity)
- Review and streamline Program processes (inspections and audits)
- Align goals and timelines for SAMHSA/DWP and Federal Partners

# Federal Drug Free Workplace Program

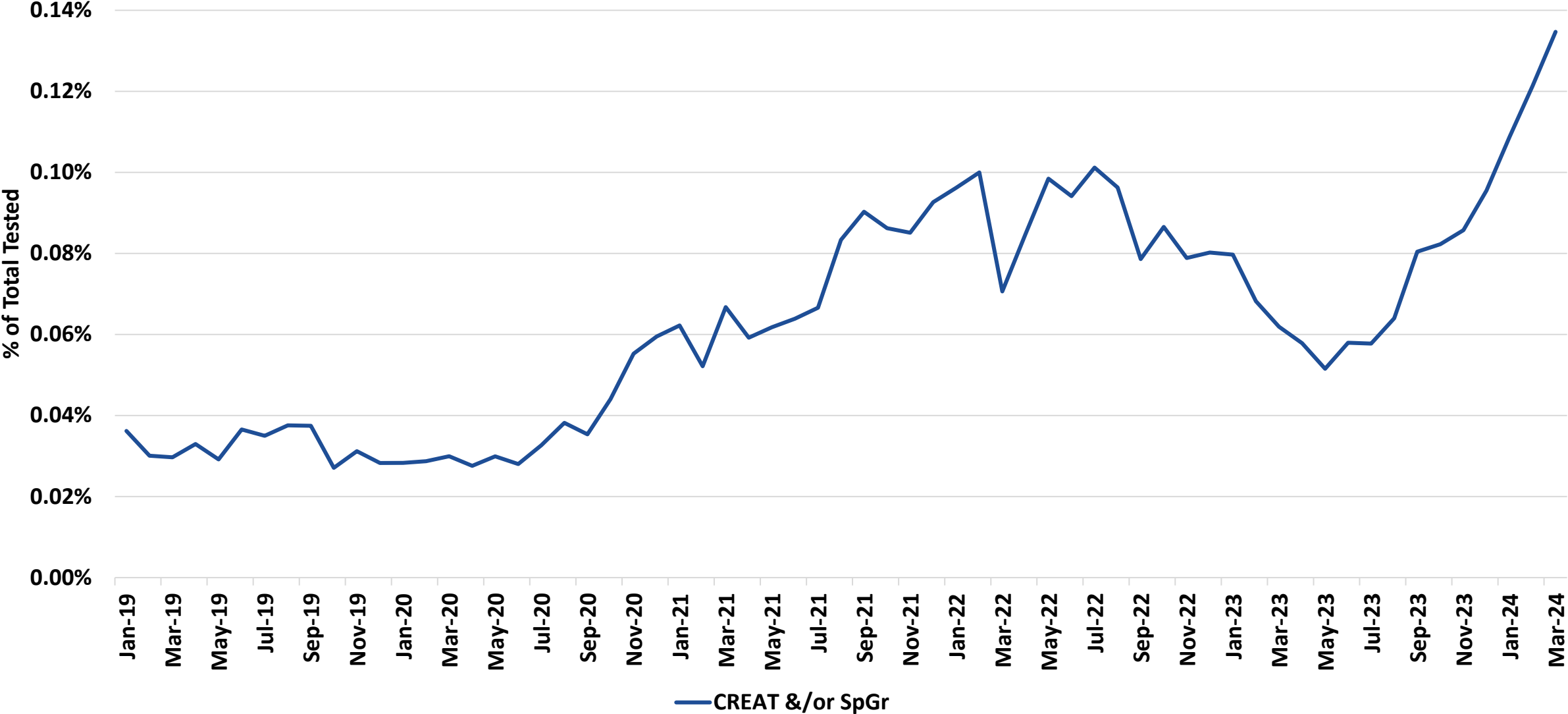


\*Alcohol, Drug Abuse and Mental Health Administration

# Specimens Reported Non-Negative by SVT Category

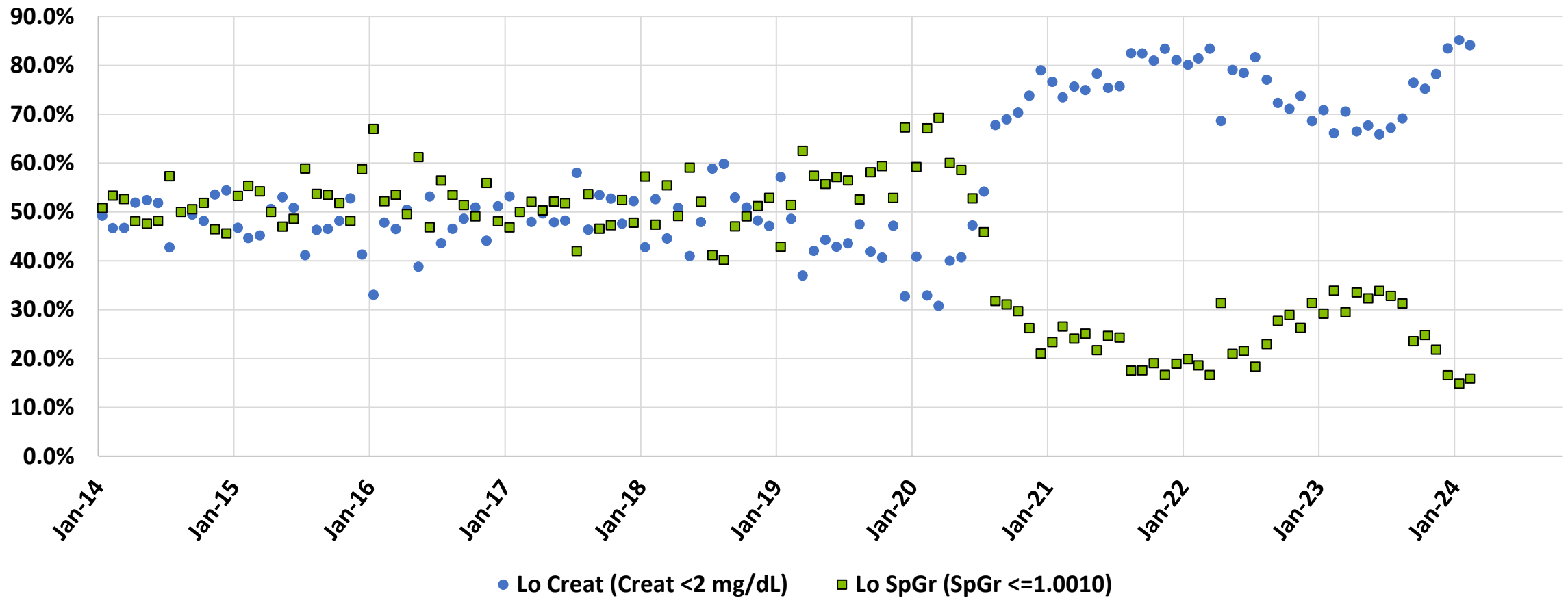


# Invalid Specimens for Creatinine / Specific Gravity

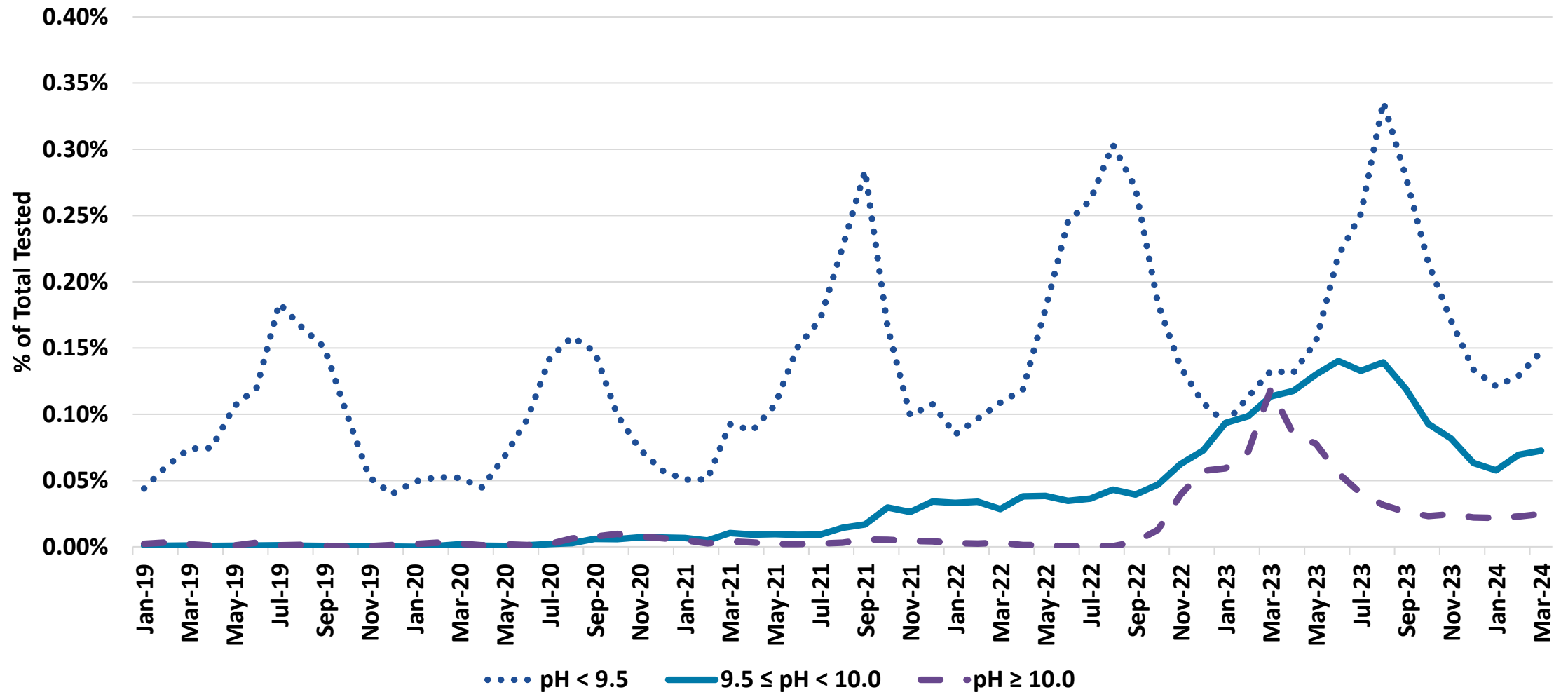


# Inconsistent Creatinine and Specific Gravity

Inconsistent Creatinine and Specific Gravity Concentration

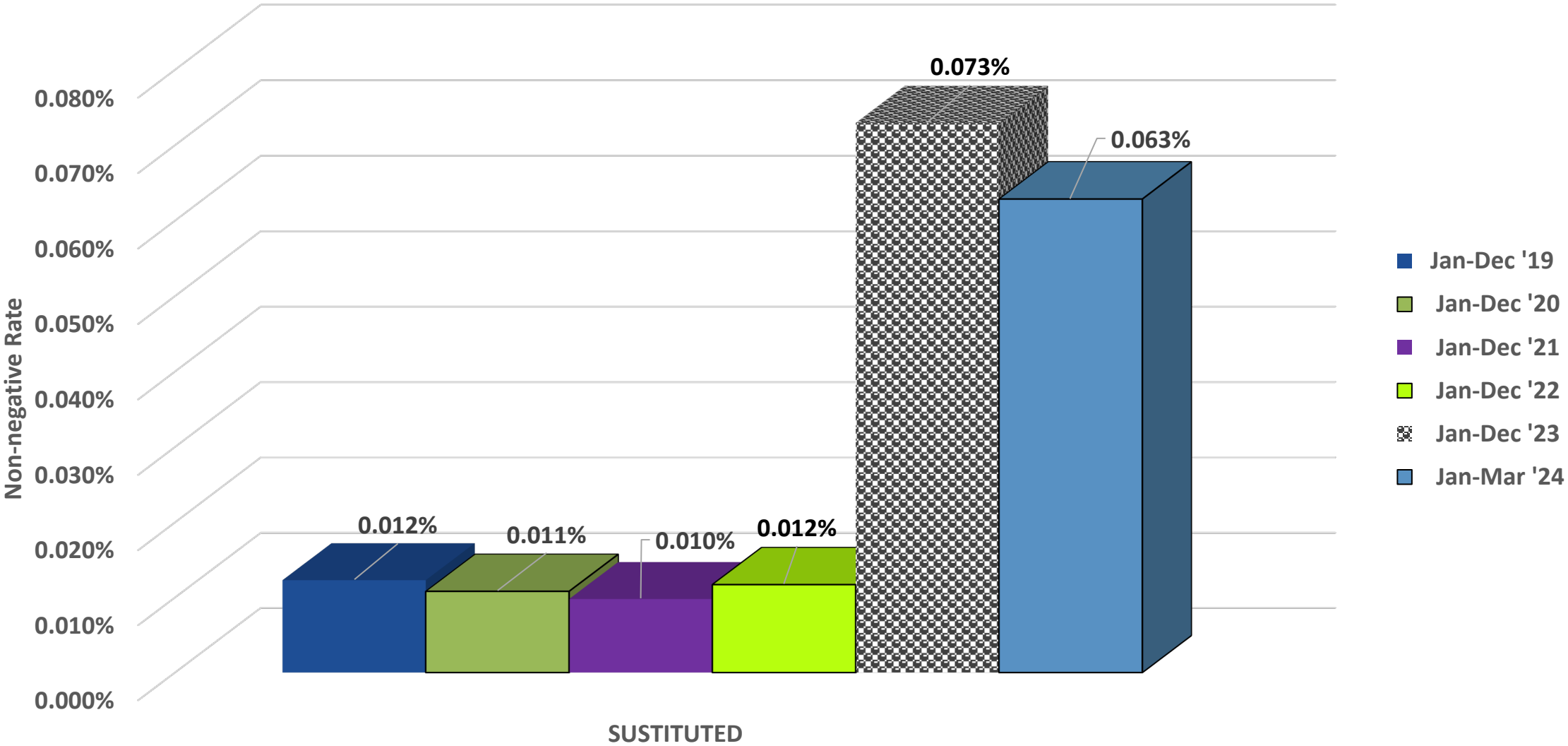


# Invalids Abnormal pH

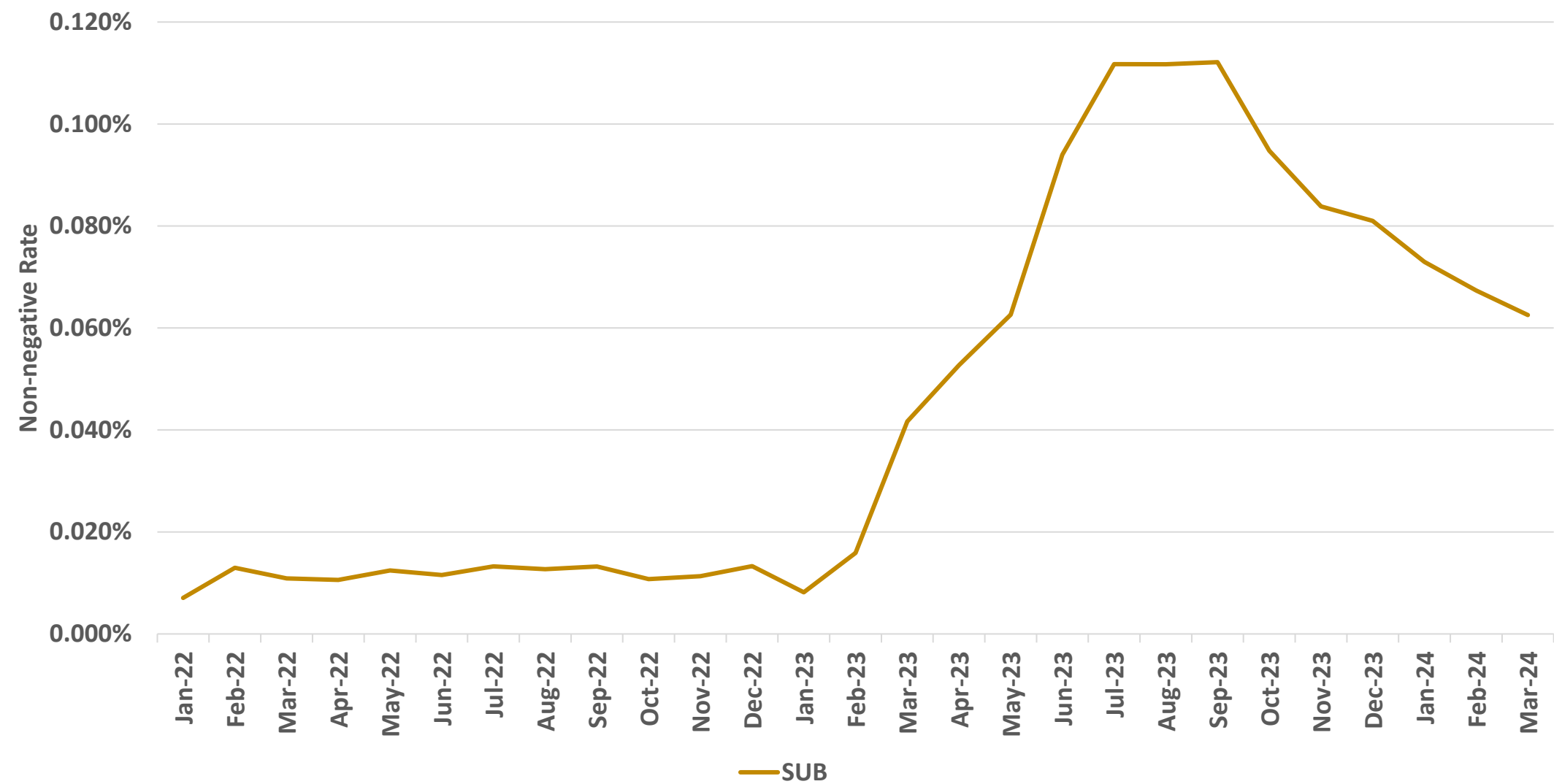




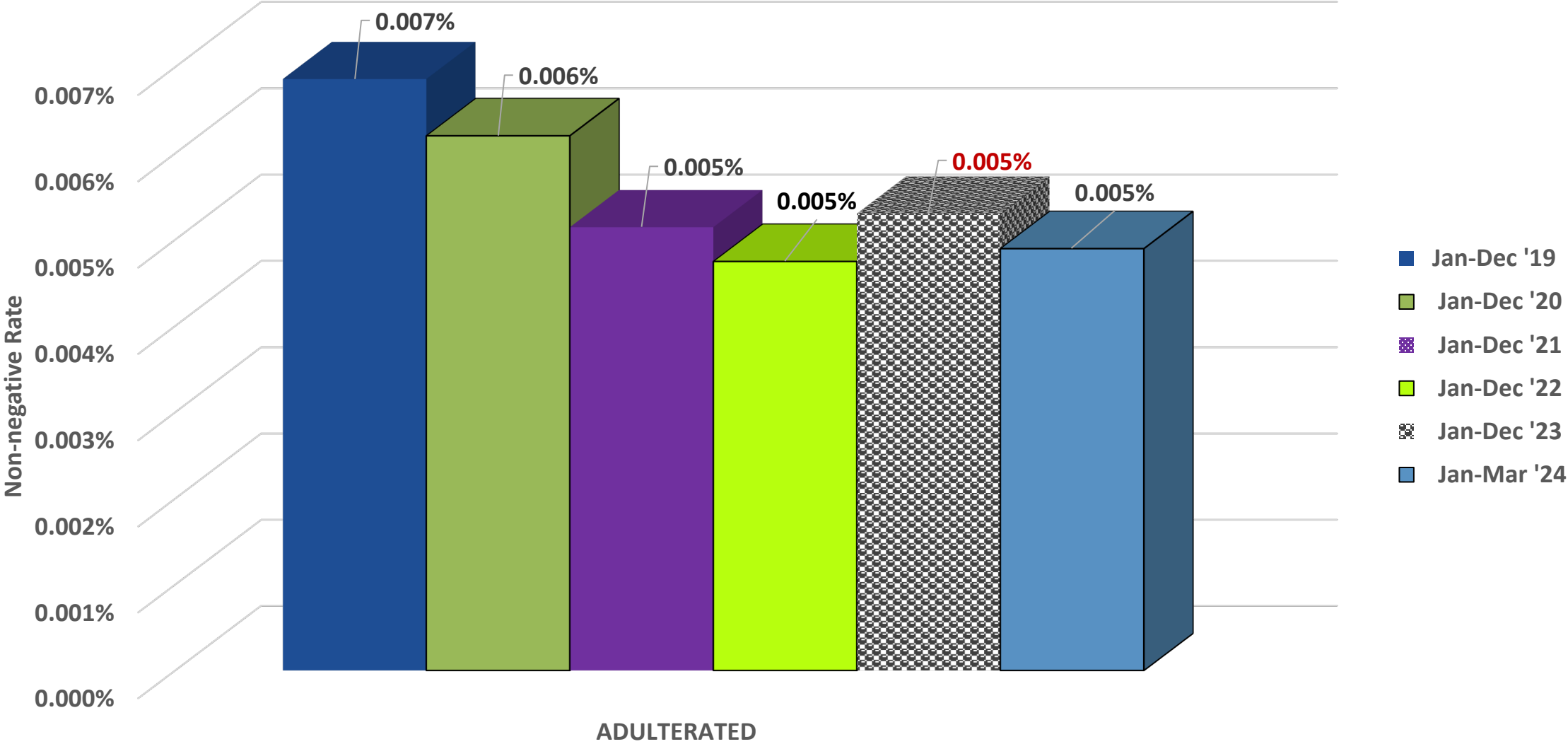
# Specimens Reported Non-Negative by SVT Category Jan 2019 – Mar 2024



# Specimens Reported Non-Negative: Substituted Jan 2022 –Mar 2024



# Specimens Reported Non-Negative by SVT Category Jan 2019 – Mar 2024



# DFWP Resources

Division of Workplace Programs (DWP) Main Website:

<https://www.samhsa.gov/workplace>

Executive Order 12564:

[https://www.samhsa.gov/sites/default/files/executive\\_order.pdf](https://www.samhsa.gov/sites/default/files/executive_order.pdf)

Public Law 100-71:

[https://www.samhsa.gov/sites/default/files/workplace/public\\_law\\_100.pdf](https://www.samhsa.gov/sites/default/files/workplace/public_law_100.pdf)

Model Plan for a Comprehensive Drug-Free Workplace Program:

<https://www.samhsa.gov/sites/default/files/workplace/ModelPlan508.pdf>

2013 Guidance for Selection of Testing Designated Positions:

<https://www.samhsa.gov/sites/default/files/workplace/09-2013-guidance-selection-tdps-2-13-17.pdf>

# ***Thank You***

## ***Division of Workplace Programs***

Please Visit our Website

**<https://www.samhsa.gov/workplace>**