

Findings from the Model Performance Evaluation Program for Rapid HIV Testing

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What is the MPEP?

- Voluntary, non-regulatory external quality assessment program for laboratory testing of public health significance
- Includes biannual surveys with challenge sample panels and periodic practice questionnaires



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Advantages for a Testing Site

- Voluntary, non-regulatory
- No charge for participation
- MPEP provides well-characterized samples
- Compare results with other laboratories using the same and different methods
- Consult with CDC MPEP staff on testing & quality assurance issues



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Advantages for Public Health

- Evaluate laboratory performance and practices
- Identify problems in performance, especially with new tests
- Resource for guidelines and recommendations
- Influence practice trends; encourage optimal performance



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Rapid HIV Challenge Samples

- Plasma from individual donors, single bleeds, seroconverters included
- Positive donors Western blot confirmed (HIV-1)
- Hepatitis B and C antigen negative
- Defibrinated and tested for bacterial contamination
- Tested with all FDA-approved rapid HIV antibody tests
- Positive challenges heat-inactivated
- Frozen panels shipped, 6 challenges/panel



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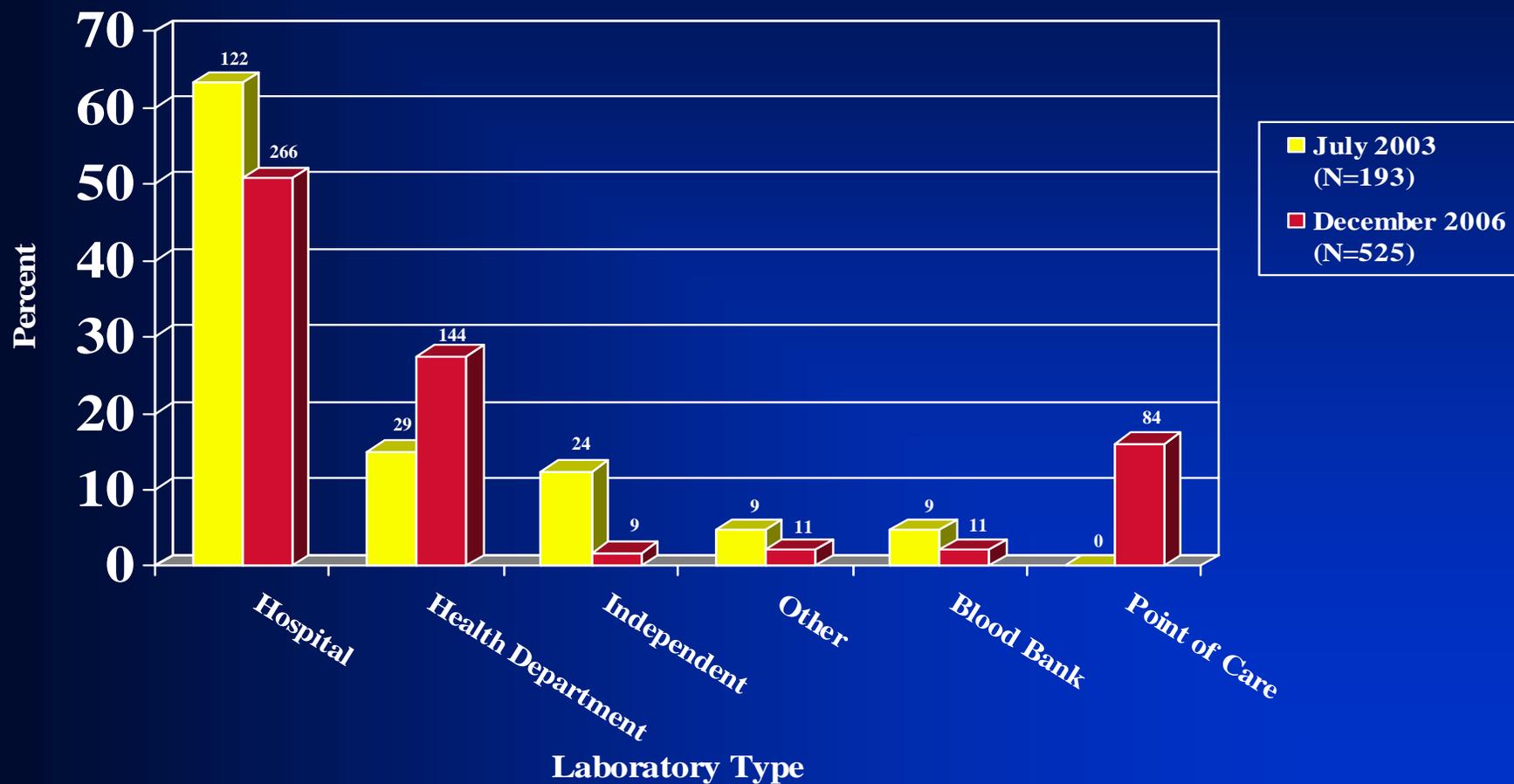
Participant Demographics



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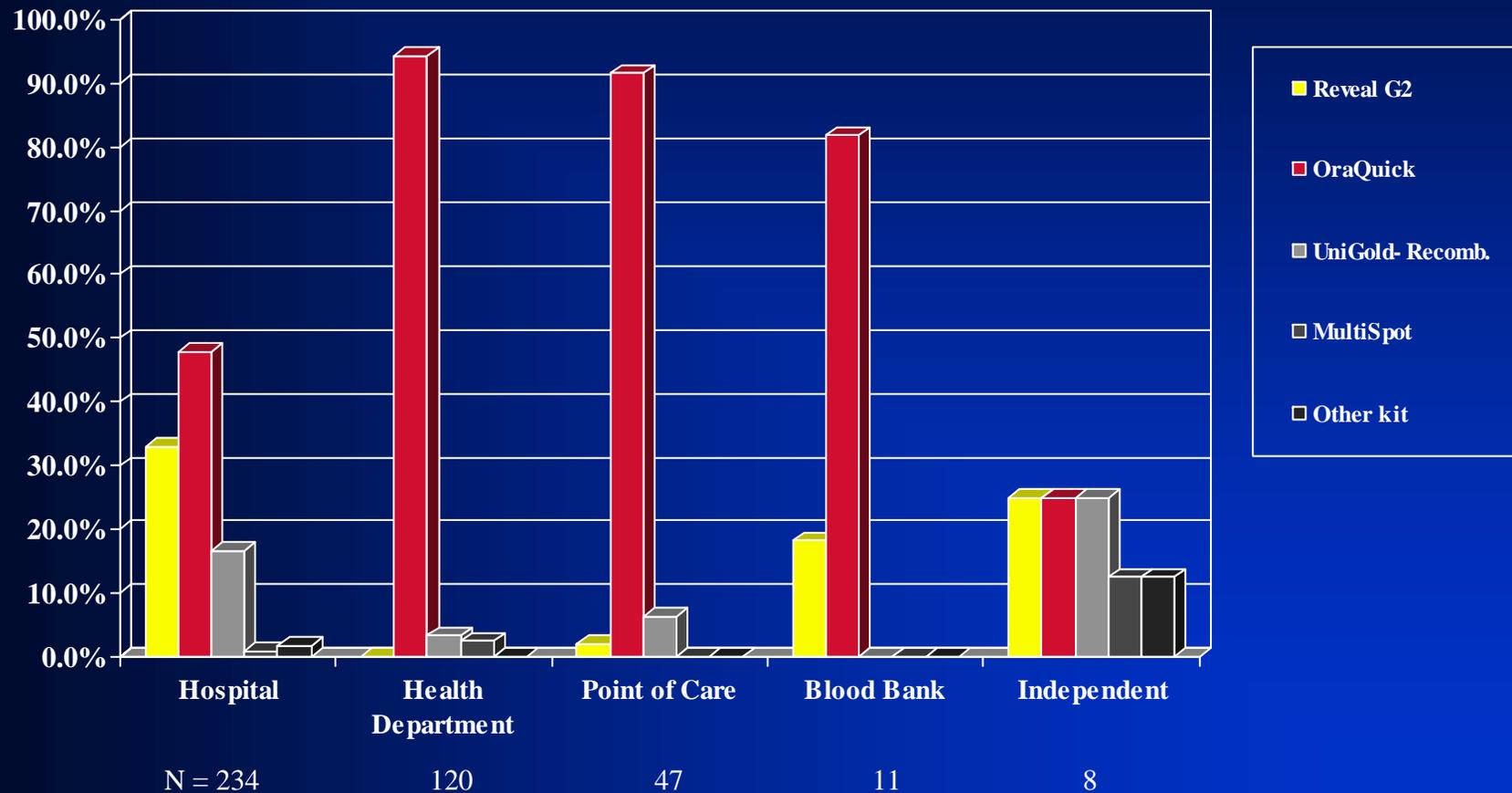
Change in Demographics of Enrolled Laboratories



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Rapid HIV Test Kits Used by Testing Sites



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Performance Statistics



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Overall Laboratory Performance

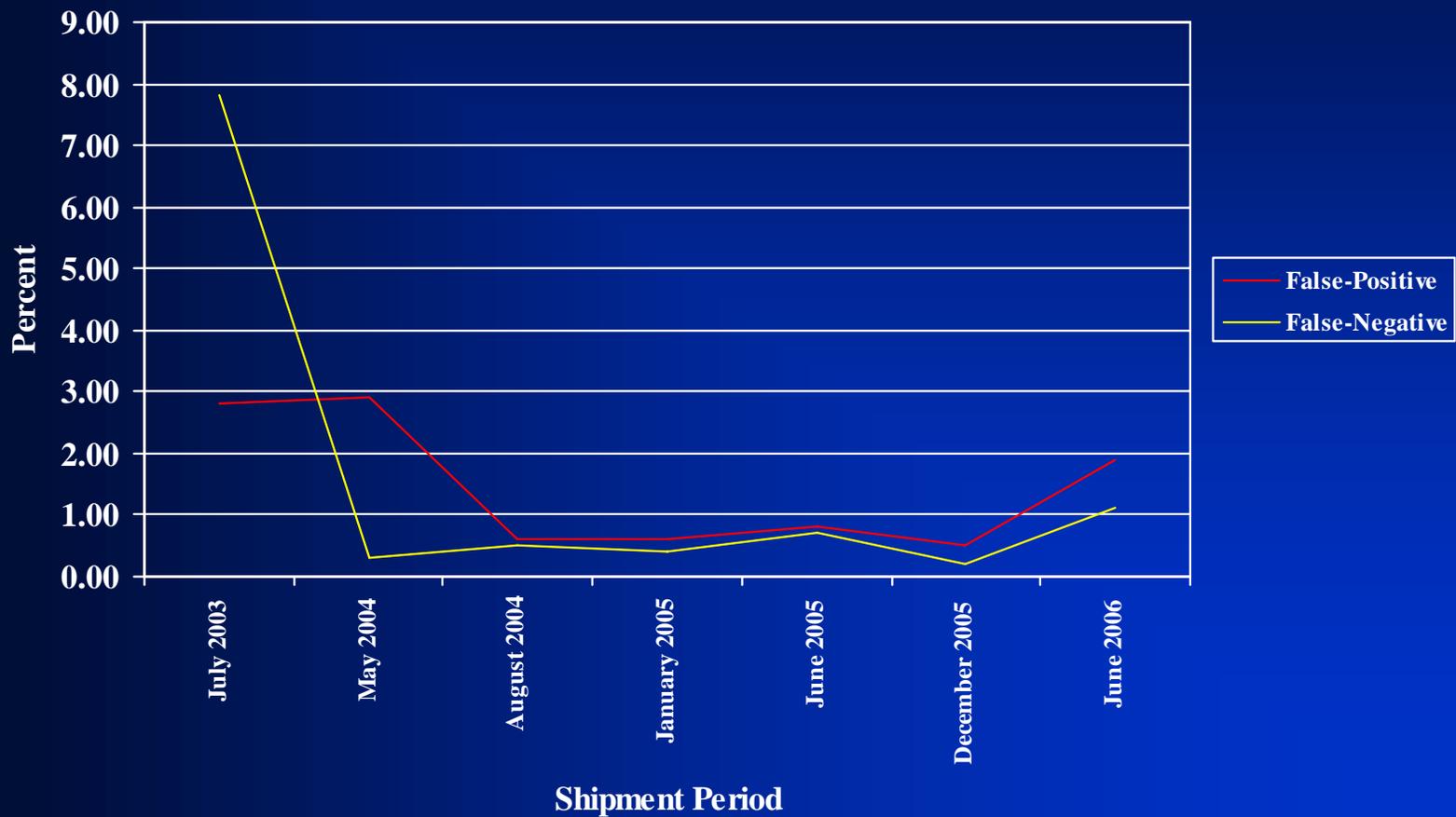
Donor	December 2005					June 2006				
	Percent Correct	Total Results	Pos.	Neg.	Indeterminate	Percent Correct	Total Results	Pos.	Neg.	Indeterminate
Negative (1 donor)	99.5%	404	2	402	0	98.1%	417	5	409	3
Positives (3 donors)	99.8%	1224	1221	2	1	98.5%	1261	1242	14	5



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False-Positive and False-Negative Rates, 2003-2006



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Problems Identified: Reasons for Errors

1. Sample mix-up
2. Transcription errors
3. Not following manufacturer's instructions
 - Sample preparation
 - Incubation time
4. Matrix effect (July 2003)



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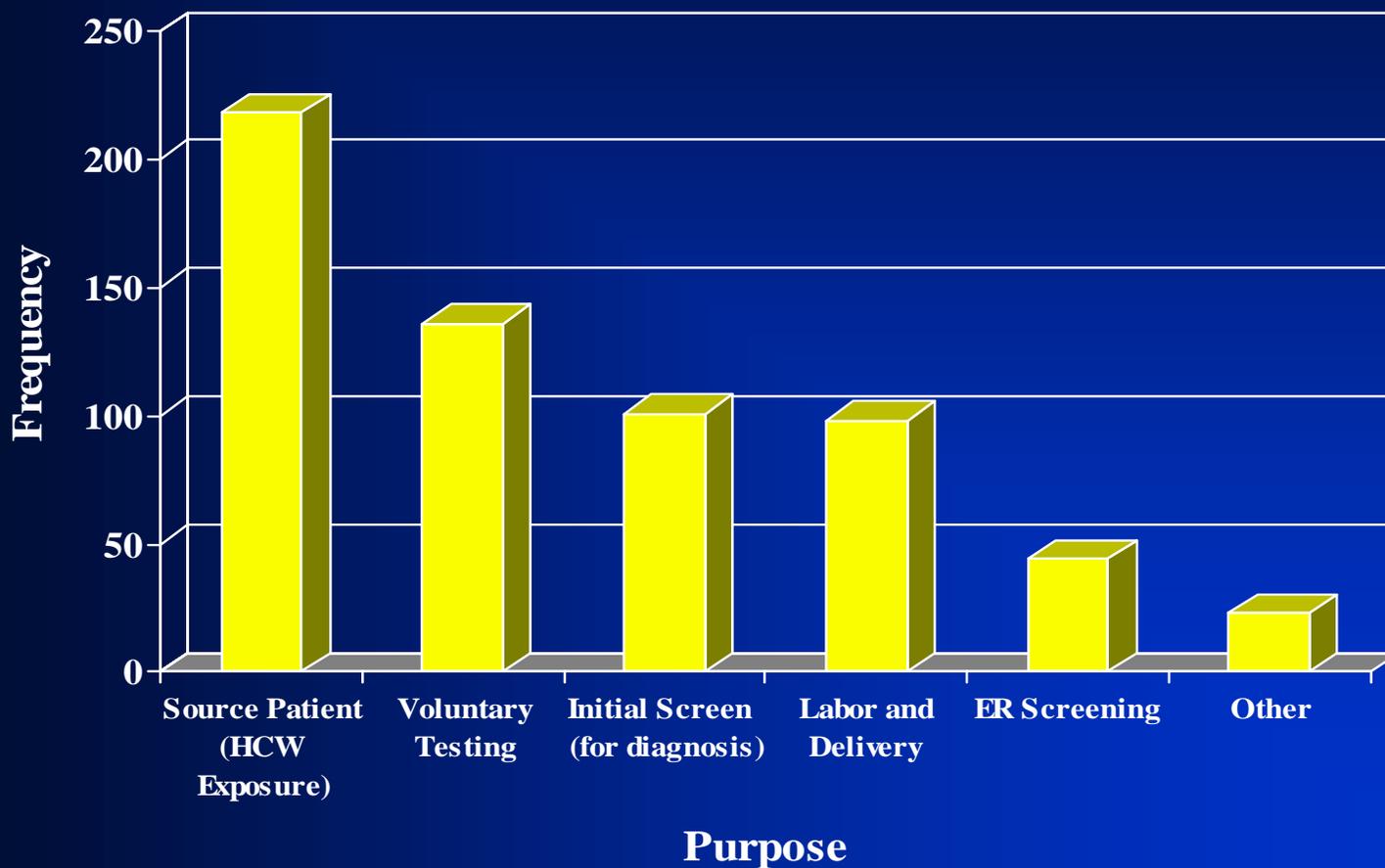
Practices



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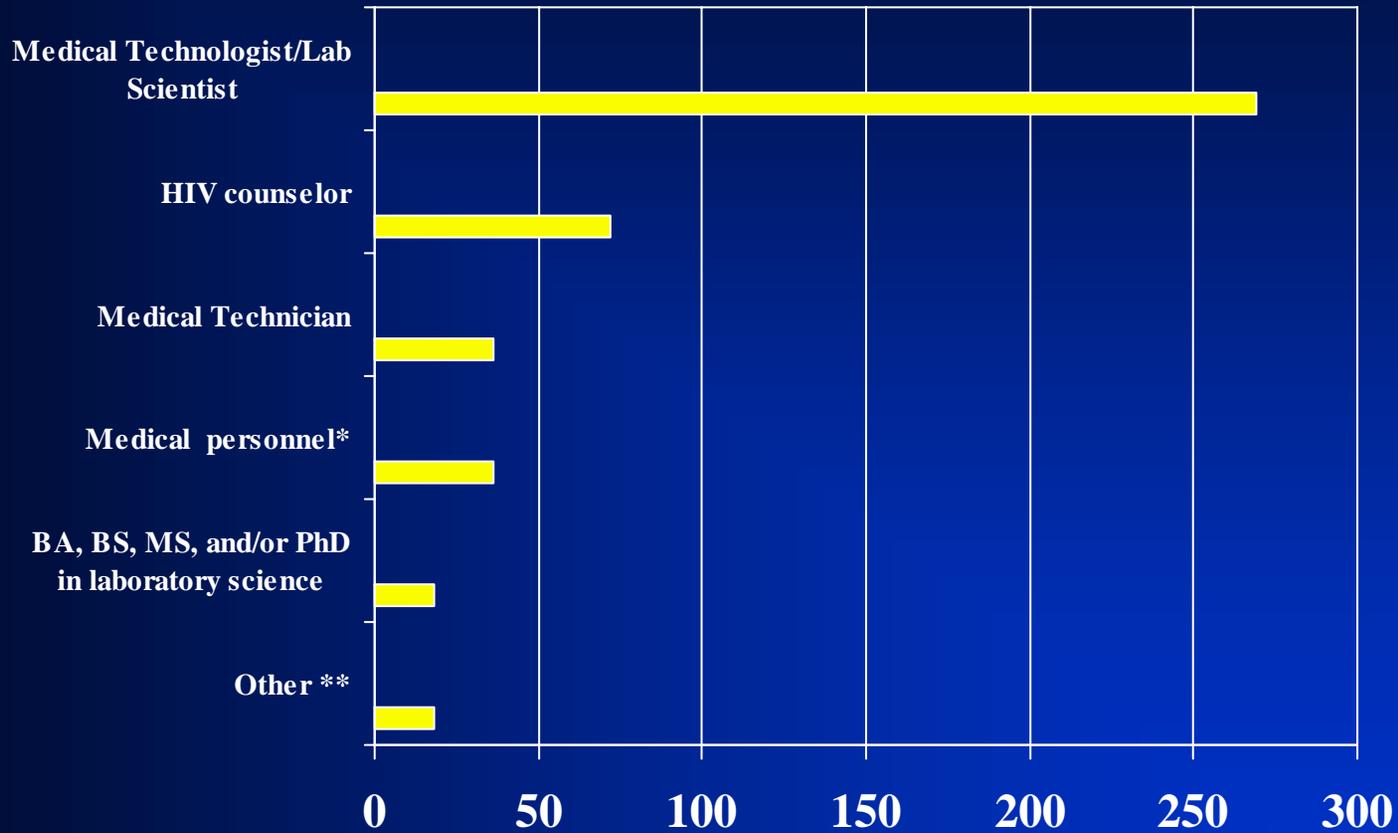
Purpose for Rapid HIV Testing



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Testing Personnel



*MD, RN, LPN, Nurse Pract., Med Asst., phlebotomist

** Supervisor, Manager, Project Coordinator, etc.

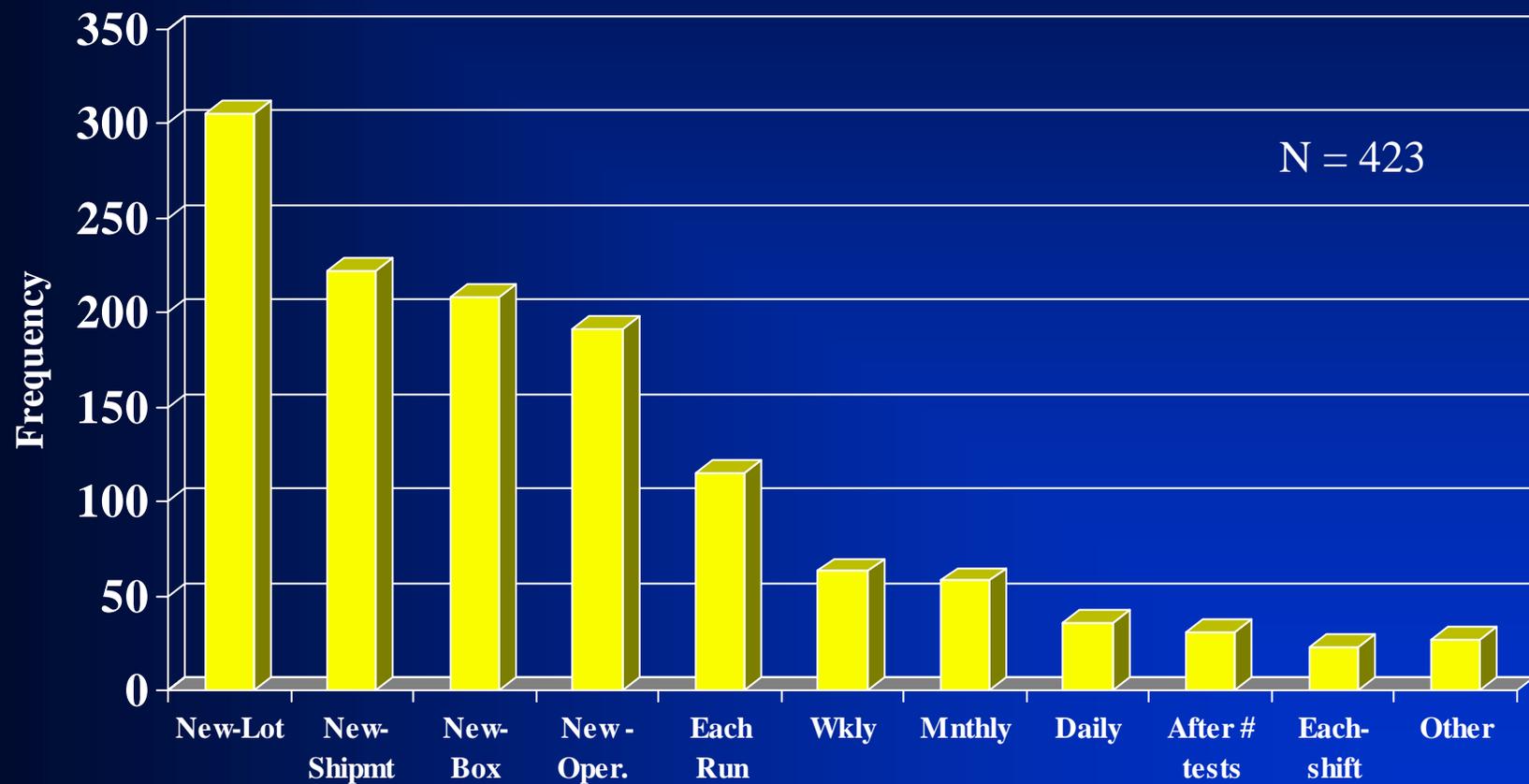
Number of Responses



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Use of QC material



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Use of Confirmatory Testing Is Confirmatory Testing Required?

	Yes	No
All Labs	301 (96.7%)	10 (3.3%)
Point of Care	33 (100.0%)	0
Blood Bank	6 (100.0%)	0
Hospital	181 (97.3%)	5 (2.7%)
Health Department	70 (95.9%)	3 (4.1%)
Other	6 (85.7%)	1 (14.3%)
Independent	5 (83.3%)	1 (16.7%)



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Types of Confirmatory Testing Used

Confirmation Method	Frequency
Western blot, sent out	333
EIA, sent out	90
EIA, our laboratory	74
2 nd rapid test, same manufacturer, our laboratory	85
Western blot, our laboratory	53
Immunofluorescence assay, sent out	18
Immunofluorescence assay, our laboratory	2
2 nd rapid test, different manufacturer, our laboratory	2
3 rd rapid test, same manufacturer, our laboratory	1
HIV PCR, in our laboratory	1
No confirmatory testing performed	7



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Acknowledgements:

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www.phppo.cdc.gov/mpep/

