



# HIV subtype and acute infection sensitivity of automated HIV Ag/Ab assays

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Teal Clocksin, MS

[tr ic o r e . o r g](http://tricore.org)

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# TriCore Reference Laboratories

8.5 million  
tests per year

ISO 15189  
accredited

12 rapid  
response  
laboratories

1 core  
reference  
laboratory

>25 patient  
care centers

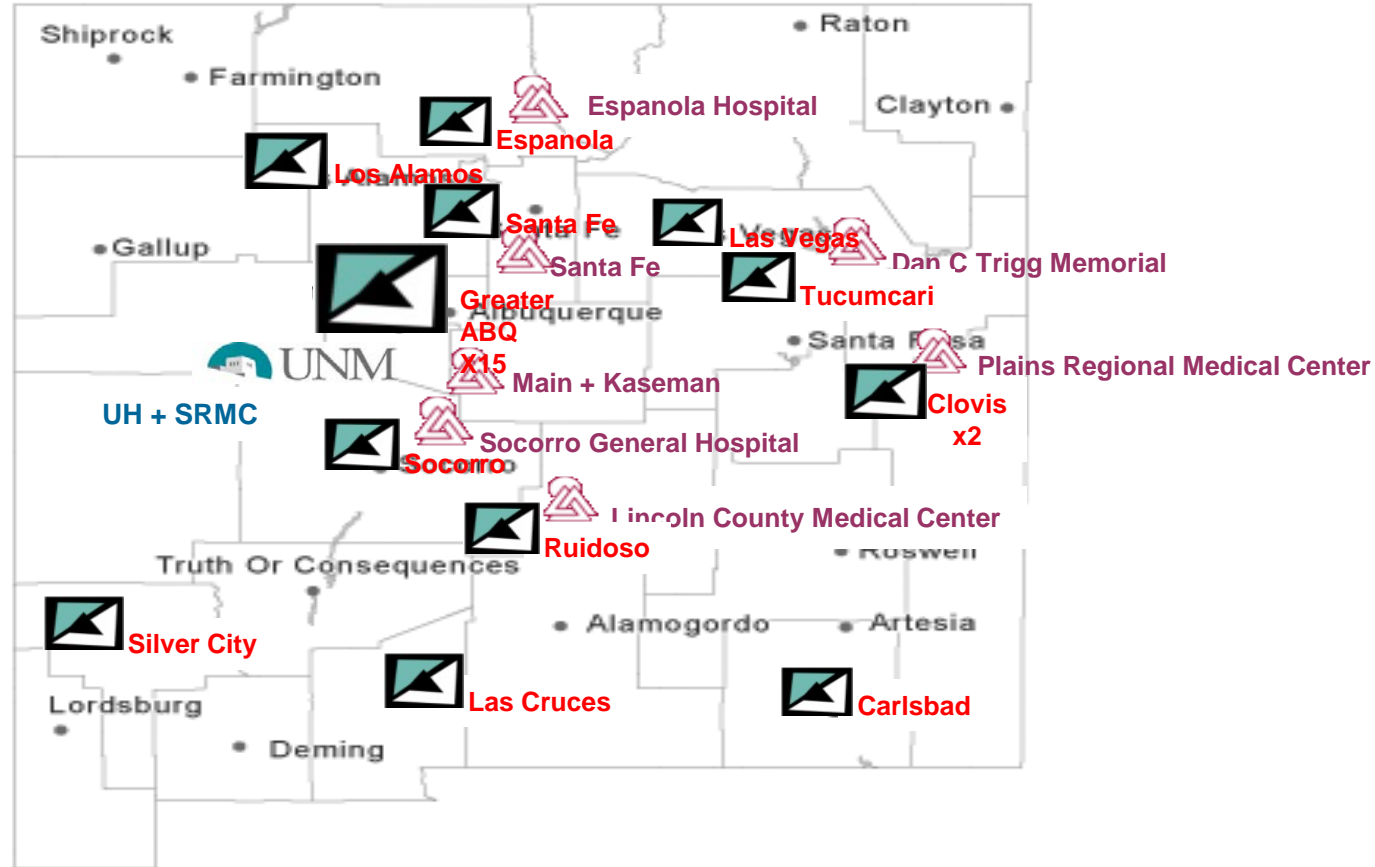
Employs  
~1,200  
individuals

# TriCore Footprint

 TriCore Patient Care Centers

 Presbyterian Hospital Locations

 UNM & SRMC



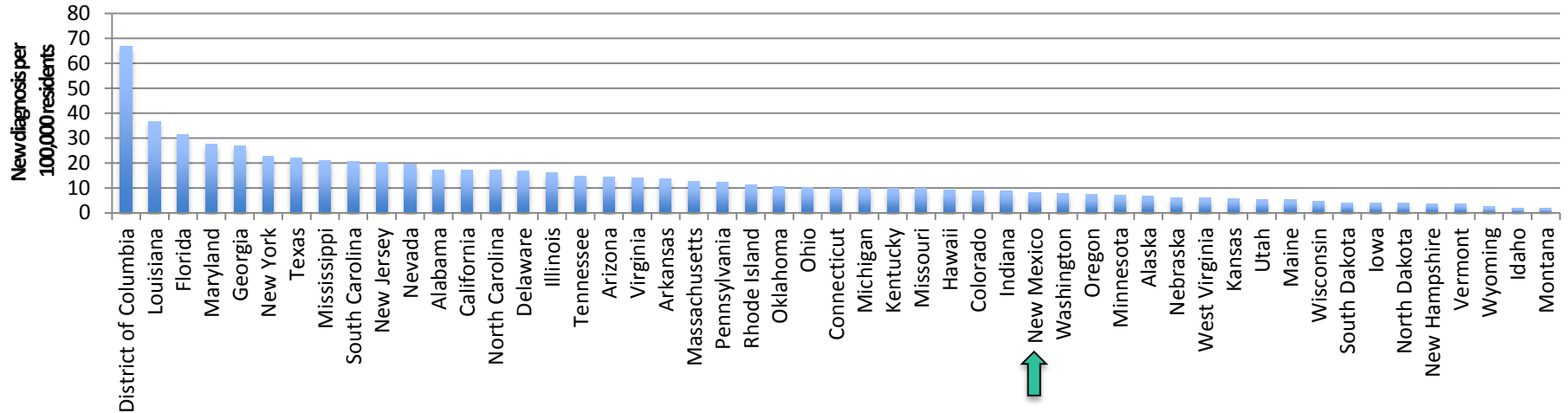
# HIV in New Mexico

193/100,000 persons<sup>1</sup>

132 new diagnosis in 2014<sup>1</sup>

89% new diagnosis are male<sup>1</sup>

Estimated 1-2 acute HIV infections/year from TriCore



1) <http://nmhealth.org/data/view/infectious/1726/>

2) <http://kff.org/hiv/aids/state-indicator/estimated-rates-per-100000-of-hiv-diagnoses-adults-and-adolescents/#>

# Objective

Determine best HIV Ab/Ag screening test for  
low prevalence state like New Mexico

- **JUNE 18, 2010 – ABBOTT ARCHITECT HIV COMBO**
  - CMIA
  - Simultaneous qualitative detection of HIV 1 p24 Ag, HIV 1 Ab and HIV 2 Ab
  - First non-NAT assay FDA approved for detection of acute HIV infections
- **JUNE 8, 2015 – SIEMENS ADVIA CENTAUR CHIV**
  - CMIA
  - Simultaneous qualitative detection of HIV 1 p24 Ag, HIV 1 Ab and HIV 2 Ab
- **JULY 23, 2015 – BIO-RAD BIOPLEX 2200 HIV AG-AB**
  - Multiplex flow immunoassay
  - Simultaneous qualitative detection AND differentiation of HIV 1 p24 Ag, HIV 1 Ab and HIV 2 Ab

# Abbott Subtype Antibody Sensitivity Challenge

## Antibody positive human samples diluted with human plasma

Subtype	Group	Abbott ARCHITECT HIV Ag/Ab Combo S/CO	ADVIA Centaur HIV Ag/Ab combo Index	Bio-Rad BioPlex HIV Ag-Ab combo HIV Ag-Ab Index
A	M	2.40	0.49	5.03
B	M	3.14	1.24	8.10
C	M	3.01	6.29	3.48
D	M	3.51	5.36	2.16
CRF01	M	1.99	1.89	2.20
F	M	1.37	2.43	1.83
G	M	2.61	1.67	8.55
CRF02	M	3.16	0.23	6.87
CRF06	M	2.43	5.38	2.19
HIV2	2	3.94	0.42	12.58
HIV2	2	5.20	1.05	11.74
Grp O	O	4.50	0.15	7.84
Grp O	O	3.99	0.30	86.01
Positives/ Total	Total	13/13	8/13	13/13

Red =  
reactive  
(index ≥1.0)

Black = non  
reactive



# Abbott Subtype Antigen Sensitivity Challenge

## Viral isolates diluted with human plasma

Subtype	Group	Abbott ARCHITECT HIV Ag/Ab Combo S/CO	ADVIA Centaur HIV Ag/Ab combo Index	Bio-Rad BioPlex HIV Ag-Ab combo Index
A	M	1.81	0.74	1.17
B	M	1.81	0.81	1.38
C	M	1.94	0.74	1.95
CRF01	M	2.02	0.61	0.54
CRF02	M	1.82	0.55	1.58
CRF06	M	1.83	0.81	1.54
D	M	1.77	0.77	1.52
F	M	1.72	0.87	1.34
G	M	1.73	0.54	0.97
H	M	2.26	0.23	1.88
J	M	2.04	0.55	3.43
HIV-2	2	1.79	0.86	28.03
HIV-2	2	1.83	0.32	4.13
Grp N	N	2.64	0.49	1.31
Grp O	O	1.67	0.58	0.21
Grp O	O	1.71	0.57	0.10
Positives/ Total	Total	16/16	0/16	12/16

# Abbott p24 Sensitivity Challenge

## WHO p24 standard diluted to indicated concentrations

Concentration	Category	Bio-Rad BioPlex HIV Ag/Ab combo HIV Ag-Ab Index	Abbott ARCHITECT HIV Ag/Ab Combo S/CO	ADVIA Centaur HIV Ag/Ab combo Index
5 IU/ml	WHO p24	27.47	6.72	2.41
2.5 IU/ml	WHO p24	12.32	3.47	1.38
1.25 IU/ml	WHO p24	6.27	1.83	0.79
0.625 IU/ml	WHO p24	3.16	0.95	0.49
0.312 IU/ml	WHO p24	1.70	0.53	0.30
Limit of Detection				
	Manufacturer	0.33 IU/ml	NA	1.05 IU/ml
	Current study	<0.312 IU/ml	0.65 IU/ml	1.76 IU/ml
	Ly, et al.	NA	1.03 IU/ml	1.90 IU/ml

# Bio-Rad Seroconversion panel challenge

## Native seroconversion panel samples

Panel member	Bleed Date	Abbott ARCHITECT HIV Ag/Ab Combo S/CO	Siemens Centaur HIV Ag/Ab combo Index	Bio-Rad BioPlex HIV Ag/Ab combo HIV Ag-Ab Index
A-08	10/18/99	0.73	0.38	1.37
A-09	10/23/99	62.15	13.00	153.94
B-05	11/26/97	0.61	0.44	1.49
B-06	11/28/97	2.07	1.30	6.55
C-08	3/8/98	0.99	0.51	2.08
C-09	3/11/98	9.37	3.59	27.69

# Analytical vs Clinical Sensitivity

	Analytical Sensitivity			Clinical Sensitivity	
	Antigen Subtype Panel	Antibody Subtype Panel	WHO p24 LOD (IU/ml)	Earliest bleed date detected (Panel A, Panel B, Panel C)	Retrospective samples (true/total)
Architect	16/16	13/13	0.65	(10/23, 11/28, 3/11)	67/67
Centaur	0/16	8/13	1.76	(10/23, 11/28, 3/11)	67/67
BioPlex	12/16	13/13	<0.312	(10/18, 11/26, 3/8)	67/67

# Subtypes in New Mexico

Based on genotyping/phenotyping data non-B subtypes  
are nearly non-existent in New Mexico

Two A subtypes have been identified in Western New  
Mexico – from patient with African country of birth and  
spouse

# HIV-1 Subtype B

## Diluted antibody-positive sample

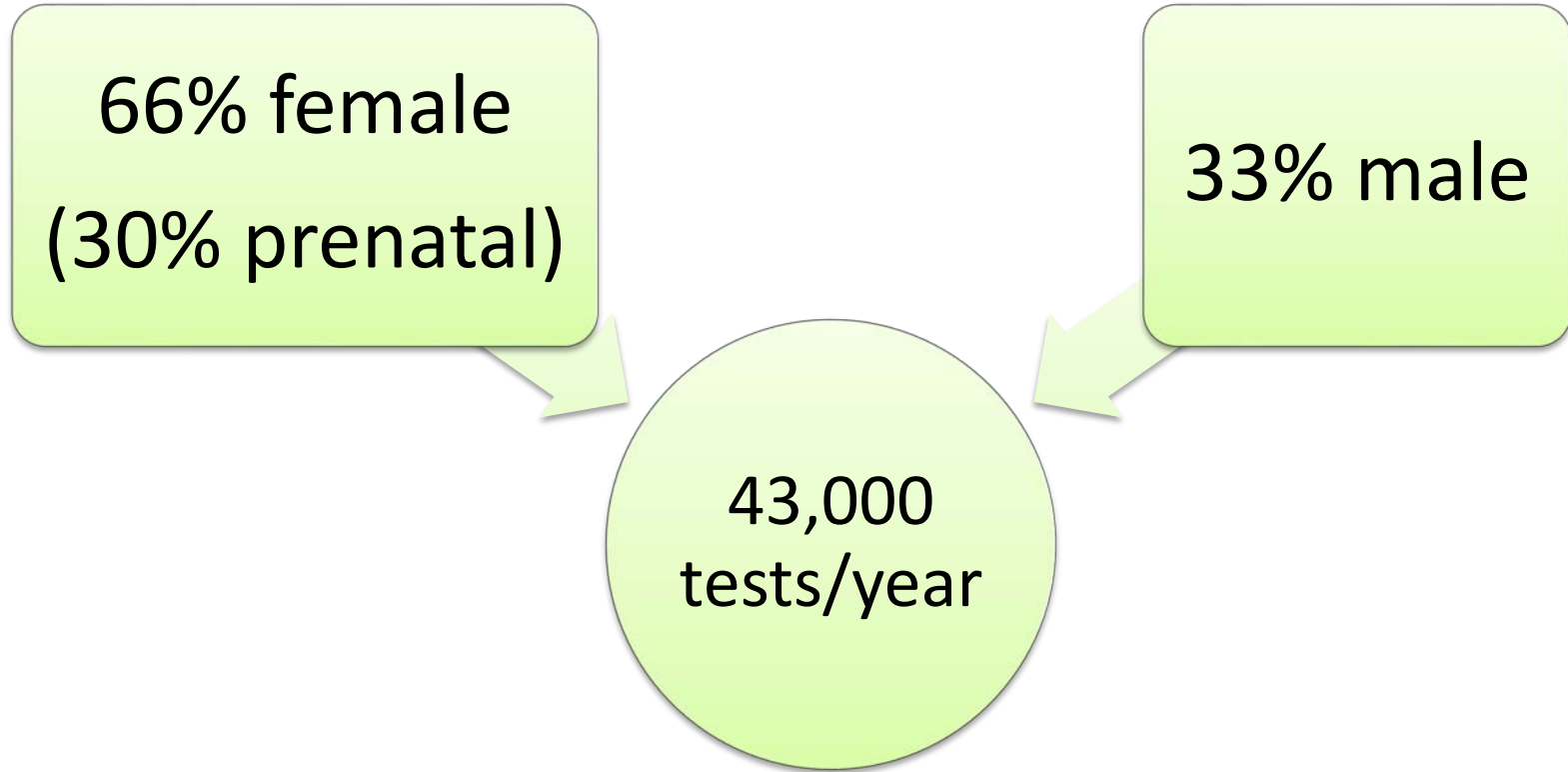
Subtype	Group	Abbott ARCHITECT HIV Ag/Ab Combo S/CO	ADVIA Centaur HIV Ag/Ab combo Index	Bio-Rad BioPlex HIV Ag-Ab combo HIV Ag-Ab Index
B	M	3.14	1.24	8.10

## Diluted viral isolate sample

Subtype	Group	Abbott ARCHITECT HIV Ag/Ab Combo S/CO	ADVIA Centaur HIV Ag/Ab combo Index	Bio-Rad BioPlex HIV Ag-Ab combo Index
B	M	1.81	0.81	1.38

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# HIV Workload at TriCore



# Instrument Differences

Platform	Full Automation Connectivity	HIV Assay Time	Specimen Volume	Auto-repeats	Specimen types
Architect i200SR	Yes	29 min	150 ul	Yes	Serum/Plasma
Centaur XP	Yes	42 min	100 ul	Yes	Serum
BioPlex 2200	Yes*	64 min	350 ul**	No	Serum/Plasma

\*In US Inpeco only

\*\*Includes dead volume



# HIV Workflow at TriCore

Platform	Track Connected?	Operational Hours	Sample Types	95% TAT
BioPlex	No	2 shifts 5 days/week	Serum/Plasma	48.3 hours
Centaur	Yes	24/7	Serum	4.2 hours



# Conclusion

- We selected the Centaur
  - Overall HIV prevalence in NM
  - AHI rate
  - B subtype in NM
  - TAT (screen + confirmation results <24hrs)
- Other laboratories
  - Base decision on prevalence, subtype prevalence, workflow needs

Specificity!

# Thanks!

- Dr. Steve Young
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