SMILE

Patient Safety Monitoring in International Laboratories

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International QA/QC Coordinators, SMILE

ACKNOWLEDGEMENTS

DAIDS - Daniella Livnat and Mike Ussery

***This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under contract No.* HHSN266200500001C, *titled* Patient Safety Monitoring in International Laboratories.**

Johns Hopkins University – SMILE Staff

Dr. Robert Miller - Principal Investigator

Barbara Parsons - Operations Manager

Kurt Michael - Project Manager

Who is SMILE?

- Contract resource between NIH/NIAID-DAIDS & Johns Hopkins University
- Staff of 12 with a wide range of laboratory experience

Major Functions of SMILE

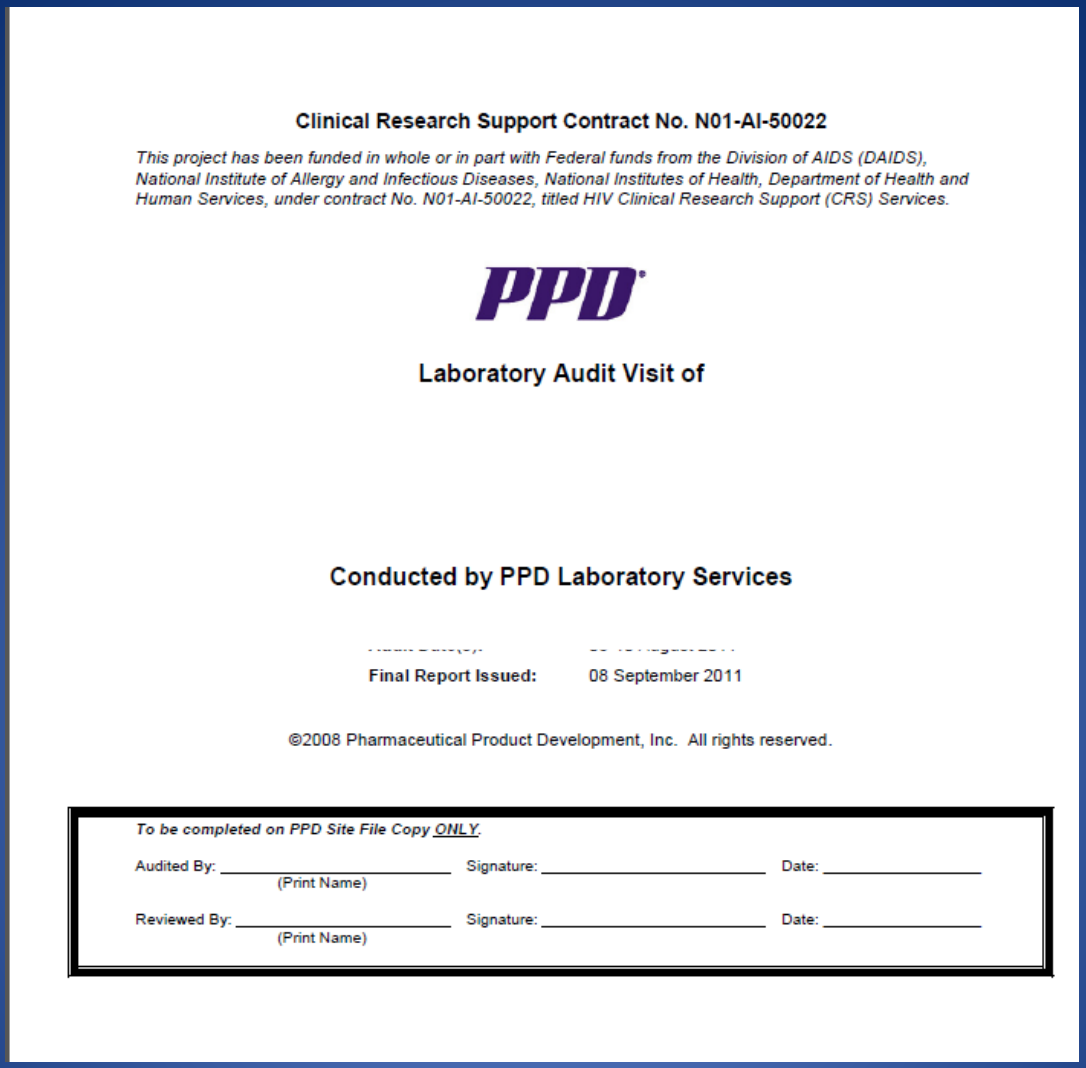
- Action Plans
- Validation Review
- Protocol Analyte Lists
- EQA Review
- Investigations
- Resources/Training

Who are the partners?

Laboratory Audits

Independent assessments are performed annually by PPD or DAIDS

Based on the standards of Good Clinical Laboratory Practice (GCLP)



Clinical Research Support Contract No. N01-AI-50022

This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under contract No. N01-AI-50022, titled HIV Clinical Research Support (CRS) Services.

PPD

Laboratory Audit Visit of

Conducted by PPD Laboratory Services

Final Report Issued: 08 September 2011

To be completed on PPD Site File Copy ONLY.

Audited By: _____ Signature: _____ Date: _____
(Print Name)

Reviewed By: _____ Signature: _____ Date: _____
(Print Name)

- Ordered by the DAIDS POC for your site
- Pre-visit checklist sent about 2 weeks before audit

IX. Test and Control Articles, *continued*

C. QC Materials

Comments:
3. QC materials were not dated with new expiration dates after opening or reconstitution; however, materials were labeled with the opened or preparation dates, and the stability of the materials was documented in the written procedures.

D. Calibration Materials

1.	Are calibration materials utilized by the laboratory? (If "No", skip to Section E.)	Yes ☒	No ☐	Comments ☐
2.	Are all calibration materials dated within the manufacturer's assigned expiration dates?	Yes ☒	No ☐	Comments ☐
3.	Are all calibration materials properly stored, as required by the manufacturer?	Yes ☒	No ☐	Comments ☐
4.	Are all calibration materials properly labeled to indicate identity, lot number, storage requirement, date prepared/reconstituted, and expiration date?	Yes ☐	No ☒	Comments ☒

Comments:
4. Calibration materials were not dated with new expiration dates after opening or reconstitution; however, materials were labeled with the opened or preparation dates, and the stability of the materials was documented in the written procedures.

E. Reagent/Testing Kits

1.	Are all reagent/testing kits dated within the manufacturer's assigned expiration dates?	Yes ☒	No ☐	Comments ☐
2.	Are all reagents/testing kits properly stored, as described by the manufacturer?	Yes ☒	No ☐	Comments ☐
3.	Are all reagents/solutions properly labeled to indicate identity, lot number, storage requirement, date prepared/reconstituted, and expiration date?	Yes ☐	No ☒	Comments ☒

Comments:
3. Hematology reagents were not labeled with the new expiration dates after opening; however, the reagents were consumed well within the expiry dates, according to the Hematology Coordinator, Agda Moraes.

Audits and Action Plans

1. Audit report sent to SMILE
2. Action Plan is prepared
3. SMILE returns the AP to DAIDS POC for distribution to the affiliated networks
4. Networks designate critical items
5. Action Plan and audit report sent to lab by DAIDS POC

I11

	A	B	C	D	E	F	G
1		Key					
2		Complete					
3		In Progress					
4		Status Unknown		SMILE comments in BLUE.			
5		Contingent or Critical Items		Site comments in RED.	PPD Audit Visit 15-21 December 2010		
6		Action Recommended; Follow-up Not Expected			Revised: 20 September 2011 by Anne Sholander		
7		Audit SUB-SECTION	OBSERVATION / FINDING	SUGGESTED ACTION	HISTORY	REVIEWER COMMENTS	STATUS & DATE COMPLETED
8				SECTION II- ORGANIZATION AND PERSONNEL			
9	1	II. A	**Organization chart--** a section specific organizational chart was not available for the Chemistry department. The job titles on the organizational charts were not consistent with the job titles listed in personnel records.	Create a section specific organogram for the Chemistry department. Review the organograms in all departments to ensure that the job titles listed on the organograms are consistent with the job descriptions in personnel records. Submit updated organograms to SMILE for review.	**09 Mar 11:** Chemistry Organogram received. Revised organograms for Serology, Hematology and Flow Cytometry received. (AS)		14-Mar-11
10	2	II. B. 1-8 XIII. A. 1, 5	**Availability of personnel records--** the auditor noted that personnel records were not available for review because they were stored off site and the administrative office required one week's advance notice for retrieving the files.	For future audits, please make sure that all required records are available for review by the auditor. The pre-audit checklist should serve as a reminder to request all personnel records in advance. Notify SMILE when complete.			
11	3	II. B. 1	**Personnel records--** no personnel file was maintained for the Section Coordinator in Serology. One Medical Coordinator personnel file contained no records.	Create a personnel file for the Section Coordinator in Serology. Update the personnel file for the Medical Coordinator with the appropriate records. Notify SMILE when complete.			
12	4	II. B. 2	**Job descriptions--** two job descriptions had not been signed (laboratory technicians in Flow Cytometry and Chemistry).	Ensure that the two job descriptions cited have been signed by the appropriate personnel. Notify SMILE when complete.	**20 Sept 11:** signed job descriptions submitted to SMILE. (AS)		20-Sep-11
13	5	II. B. 3	**Position profiles--** there was no job profile for the QA/QC Unit position.	Update the listing of position profiles to include the educational and experience requirements for the QA/QC Unit position. Submit the updated list to SMILE when complete.	**31 Aug 11:** Updated position profiles received. (AS)		31-Aug-11
14	6	II. B. 5	**Assay specific training records--** training provided by the manufacturers was not documented in personnel files. Ortho provided training certificates by the end of the audit. Training for the Sysmex analyzer was not documented.	Ensure that training certificates are obtained from manufacturers performing assay specific training. Document all training in the appropriate personnel files. Notify SMILE when the Sysmex training certificate is received.			
			Competency records--				

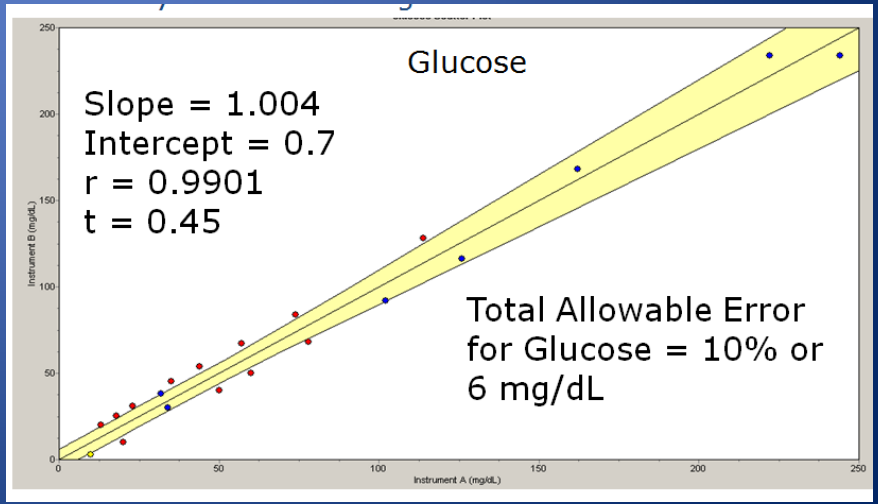
Brazil
HPTN, IMPAACT

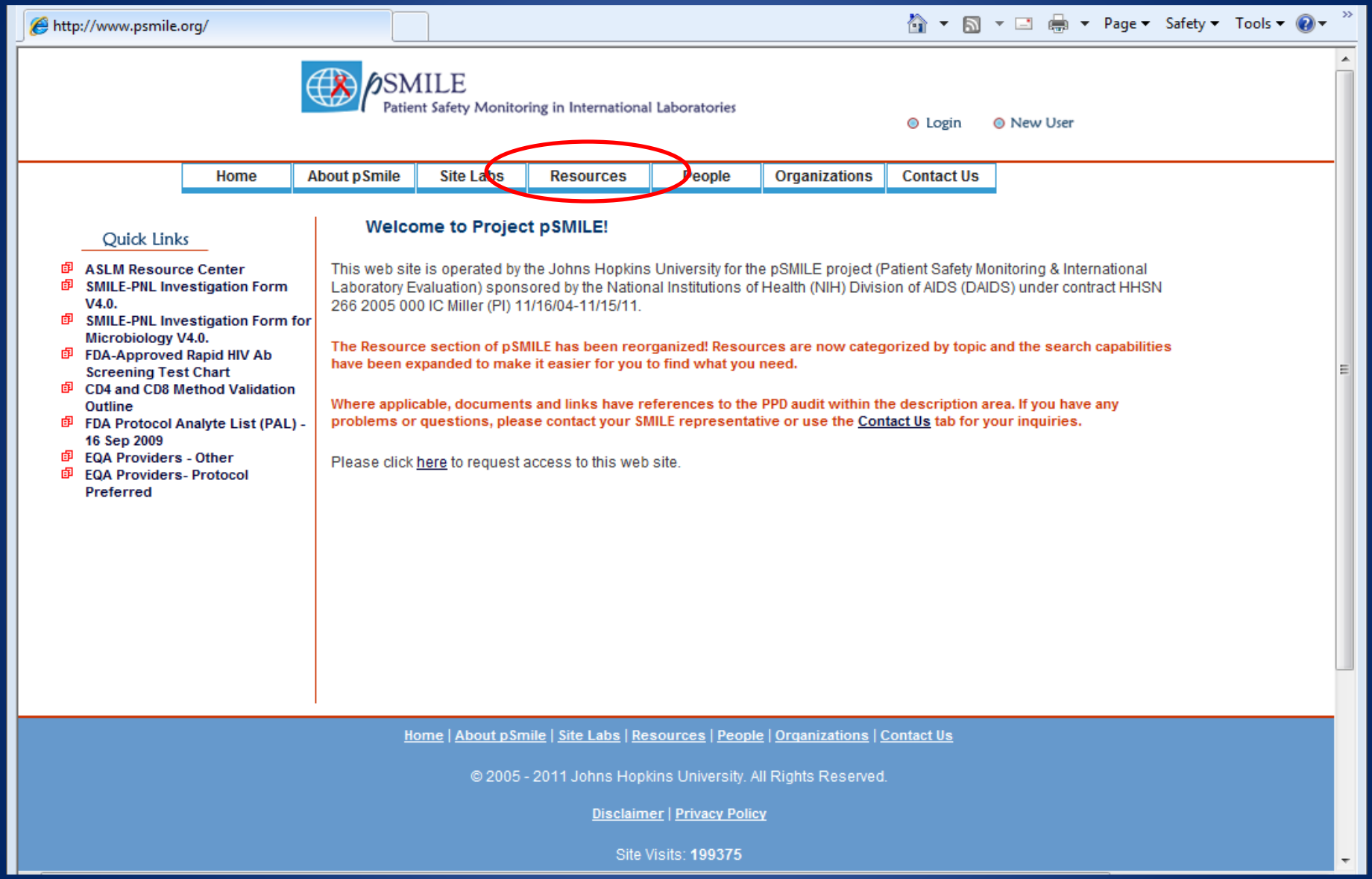
Audit Action Plan Template

Ready

Validation Review and Assistance

- Common findings from PPD audits
- New protocols/new tests
- New instrumentation
- Request from networks
- Lab moving

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ASLM Resource Center
SMILE-PNL Investigation Form V4.0.
SMILE-PNL Investigation Form for Microbiology V4.0.
FDA-Approved Rapid HIV Ab Screening Test Chart
CD4 and CD8 Method Validation Outline
FDA Protocol Analyte List (PAL) - 16 Sep 2009
EQA Providers - Other
EQA Providers- Protocol Preferred
Welcome to Project pSMILE!
This web site is operated by the Johns Hopkins University for the pSMILE project (Patient Safety Monitoring & International Laboratory Evaluation) sponsored by the National Institutions of Health (NIH) Division of AIDS (DAIDS) under contract HHSN 266 2005 000 IC Miller (PI) 11/16/04-11/15/11.
The Resource section of pSMILE has been reorganized! Resources are now categorized by topic and the search capabilities have been expanded to make it easier for you to find what you need.
Where applicable, documents and links have references to the PPD audit within the description area. If you have any problems or questions, please contact your SMILE representative or use the Contact Us tab for your inquiries.
Please click here to request access to this web site.
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Types of validation resources

- Total Allowable Error (TEa) limits table
- Validation Overviews
- Detailed validation guidelines/instructions
  - Chemistry, Hematology, HIV EIA, Rapid HIV, Viral Markers EIA, Coagulation
- Statistical calculation tools
- Plan and Summary templates for each type of assay

What are we looking for??

- Precision
- Accuracy
- Linearity (Analytical Measurement Range + Clinical Reportable Range)
- Sensitivity and Specificity
- Reference Ranges

Quantitative Validation Overview

Validation of a quantitative system (for example Chemistry analyzer or Hematology analyzer) consists of an established set of required experiments. Each laboratory should first design a validation plan describing how they will satisfy each of these requirements. The validation plan must also detail the acceptability criteria for each element. After completing all of the validation experiments, results should be compiled and filed in an organized manner. All validation records should be retained for the life of the instrument. A validation summary should be prepared that contains a place for the Laboratory Director to sign, indicating the validation has been reviewed and approved.

The following are the required components of validation:

1. **Precision** is reproducibility - the agreement of the measurements of replicate runs of the same sample. Replication experiments are performed to estimate the imprecision or random error of the analytical method. See SMILE Precision Guidelines.
2. **Accuracy** is the true value of a substance being measured. Verification of accuracy is the process of determining that the test system is producing true, valid results. See SMILE Accuracy Guidelines.
3. **Linearity** - A quantitative analytical method is said to be linear when measured results from a series of sample solutions are directly proportional to the concentration or activity in the test specimens. This means that a straight line can be used to characterize the relationship between measured results and the concentrations or activity levels of an analyte for a determined range of analyte values. See SMILE Linearity Guidelines.
4. The **Analytical Measurement Range (AMR)** is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. AMR validation is the process of confirming that the assay system will correctly recover the concentration or activity of the analyte over the AMR. The manufacturer defines the AMR – but it is the laboratory's responsibility to verify it. See SMILE AMR and CRR Guidelines.
5. The **Clinical Reportable Range (CRR)** is the range of analyte values that a method can report as a quantitative result, allowing for specimen dilution, concentration or other pretreatment used to extend the AMR. The laboratory should establish a CRR that covers the range of a Grade 4 Adverse Event on the DAIDS Toxicity Table

For each of the required elements…

- Minimum number of samples tested
- Appropriate samples selected
- Comparison to a previously validated method
- Evaluation criteria clearly stated
- Evidence of comparison to manufacturer's specifications
- Raw data that supports conclusions

SMILE
Johns Hopkins University
Baltimore, MD USA

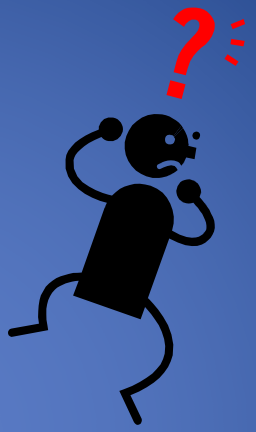
SMILE Chemistry Precision Requirements

PRECISION is reproducibility - the agreement of the measurements of replicate runs of the same sample. Replication experiments are performed to estimate the imprecision or random error of the analytical method.

I. Short -Term (Within Run/Day)
   A. Sample:
      1. Two levels (Low / High or Normal / Abnormal)
      2. Patient or quality control
   B. Testing: Run each sample 20 times on the same run, if possible, or at a minimum within the same day
   C. Acceptability criteria:
      1. Calculate the coefficient of variation (CV) for each level using 20 data points.
      2. Compare to manufacturer's stated precision claims found in the package insert.
      3. If manufacturer's precision cannot be met, it is acceptable to attain precision that is <25% of SMILE criteria for total error. Refer to the SMILE Precision Requirements Appendix 1 SMILE Chemistry TE Table.
      4. If Short -Term precision is unacceptable, consult instrument manufacturer for assistance.

II. Long-Term (Between Day)
   A. Sample:
      1. Two levels (Low/High or Normal/Abnormal)
      2. Patient or control serum. A lab may already have this data on hand from their daily QC runs.
   B. Testing: Run each sample two times per day for 10 days for a minimum of 20 total data points for each level of material used.
   C. Acceptability criteria:

What is an auditor looking for??



- All of the above PLUS…
- All data summarized in an easy-to-understand, organized report
- Raw data that supports the conclusions
- LABORATORY DIRECTOR SIGNATURE

Insert Lab Header here
Include full name and address of Lab

Validation Summary Report

Purpose: ☐Validation ☐Re-Validation ☐Other:

Description of Equipment/Process:

Equipment/Process: Insert full name of analyzer (ex: Cobas Integra 400+)

Serial Number: Insert instrument serial number

Location: Insert name of lab, city, state and country

Date: Insert date range of validation studies

FDA Approval Status: ☐Approved ☐Not approved

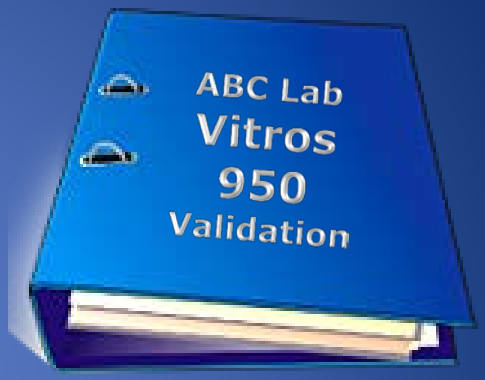
Procedure:

Refer to the insert lab name Validation Plan for insert instrument name
Ex: Refer to the XYZ Lab Validation plan for Cobas Integra 400

Results: All raw data reports and statistical analysis can be found in the insert instrument name Validation binder.

1. Precision- refer to tab A

Analyte	Expected Results		Observed Results		Acceptability
			Between Day		
	Manufacturer's Precision	33% of CLIA	Normal Control CV%	Abn Control CV%	
Ex:ALT	3.3%	6.6%	3.8%	4.3%	Acceptable



Reference Range Approval
Medical Director: _____ Date: _____
Insert Medical director name here

Method Approval

Approved / Not Approved

If not approved, provide recommendations/corrective actions below.

Laboratory Director: _____ Date: _____
Insert Lab director name here

Prepared by: _____ Date: _____
Insert name and title here

Protocol Analyte List (PAL)

- Protocol analytes
- Instrumentation in use
- FDA Approval status
- Back-up plans
- Specimen flow

Laboratory Name: 7 CLINICAL TRIALS ON SITE LABS & XXX CENTRAL ROUTINE LAB & ABC/QRS DURBAN & JHB

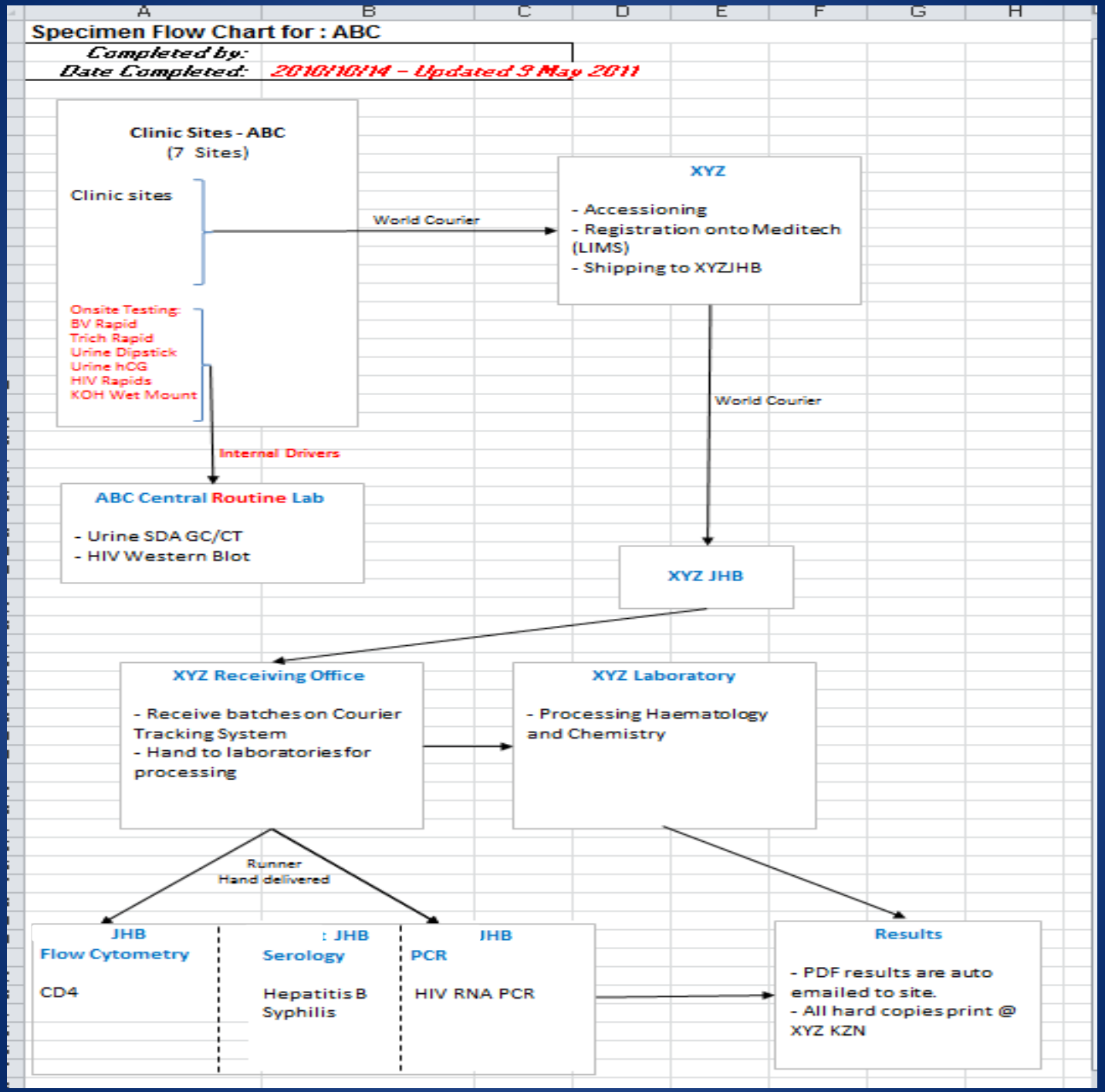
Protocol: MTN003

Completed By:

Date Completed: 9-May-11

Please fill in as much detailed information as you can provide. Please add any assays that are missing.

Assay	Primary Instrument				Primary Method/Reagent Kit								
	Instrument Name	Instrument Manufacturer	Instrument Model Number	FDA Approved (Yes/No/Don't Know)	Method/Kit Name	Method/Kit Manufacturer	Method/Kit Product Number or Product Code	FDA Approved (Yes/No/Don't Know)	Primary laboratory performing testing for this	External QA provider	Frequency of EQA	EQA Panel Details	
Chemistry													
ALT (SGPT)	COBAS INTEGRA	ROCHE	400 PLUS	FDA/CE	(IFCC), without pyridoxal-5'-phosphate	ROCHE	20764957	FDA/CE	ABC Lab JHB	CAP & THISTLE	3 per yr / 1 every two wks	CAP C3 X 5 MEMBER	
AST (SGOT)	COBAS INTEGRA	ROCHE	400 PLUS	FDACE	(IFCC), without pyridoxal-5'-phosphate	ROCHE	20764949	FDA/CE	ABC Lab JHB	CAP & THISTLE	3 per yr / 1 every two wks	CAP C3 X 5 MEMBER	
Phosphate (inorganic)	COBAS INTEGRA	ROCHE	400 PLUS	FDA/CE	Phosphomolybdate UV /Integra 400plus / Roche	ROCHE	3183793	FDA/CE	ABC Lab JHB	CAP & THISTLE	3 per yr / 1 every two wks	CAP C3 X 5 MEMBER	
Creatinine	COBAS INTEGRA	ROCHE	400 PLUS	FDA/CE	Jaffé Compensated	ROCHE	20764345	FDA/CE	ABC Lab JHB	CAP & THISTLE	3 per yr / 1 every two wks	CAP C3 X 5 MEMBER	
Urinalysis													
Dipstick Urinalysis	N/A	N/A	N/A	N/A	Multi-stix 9, Uristix 4 and 2	Siemens	N/A	YES	XYZ Clinics	CAP	Twice Annually	CMM	
Urine β-hCG	N/A	N/A	N/A	N/A	Quidel Quickvue	Quidel	BMX/97016	YES	XYZ Clinics	CAP	Twice Annually	CMM	
Hematology													
Hemoglobin	COULTER	BECKMAN COULTER	LH 750	FDA/CE	Coulter	BECKMAN COULTER	NA	FDA/CE	ABC Lab JHB	CAP	3 per yr	FH 6	
Hematocrit	COULTER	BECKMAN COULTER	LH 750	FDA/CE	calculation	BECKMAN COULTER	NA	FDA/CE	ABC Lab JHB	CAP	3 per yr	FH 6	
White Blood Cell (WBC) Count	COULTER	BECKMAN COULTER	LH 750	FDA/CE	Coulter principle	BECKMAN COULTER	NA	FDA/CE	ABC Lab JHB	CAP	3 per yr	FH 6	
Red Blood Cell (RBC) Count	COULTER	BECKMAN COULTER	LH 750	FDA/CE	Coulter principle	BECKMAN COULTER	NA	FDA/CE	ABC Lab JHB	CAP	3 per yr	FH 6	
Platelet Count	COULTER	BECKMAN COULTER	LH 750	FDA/CE	Coulter principle	BECKMAN COULTER	NA	FDA/CE	ABC Lab JHB	CAP	3 per yr	FH 6	
WBC Differential Count	COULTER	BECKMAN COULTER	LH 750	FDA/CE	VCS	BECKMAN COULTER	NA	FDA/CE	ABC Lab JHB	CAP	3 per yr	FH 6	
Bacteriology													
GC/CT	Probetec	BD	Probetec1 - PT-2402 / Probetec-2 - PT -2167	Yes	SDA	BD	Without AC – 440705 ,With AC – 440450, Controls – 440451, Diluent –	Yes	XYZ Routine Lab	CAP	Thrice Annually	HC6	
Point of Care Testing													
BV Rapid	N/A	N/A	N/A	N/A	OSOM Rapid BV	OSOM/GRYPHUS	BVB25-1	Yes	XYZ Clinics	None	None	N/A	
Trich Rapid	N/A	N/A	N/A	N/A	OSOM Rapid Trich	OSOM	181E	Yes	XYZ Clinics	CAP	Thrice Annually	VS1	
KOH Wet Mount	N/A	N/A	N/A	N/A	Manual KOH preparation	N/A	N/A	N/A	XYZ Clinics	CAP	Thrice Annually	CMM	


Specimen Flow Chart for : ABC
Completed by:
Date Completed: 20101101l4 – Updated 3 May 2011
Clinic Sites - ABC
(7 Sites)
Clinic sites
Onsite Testing:
BV Rapid
Trich Rapid
Urine Dipstick
Urine hCG
HIV Rapids
KOH Wet Mount
World Courier
XYZ
- Accessioning
- Registration onto Meditech (LIMS)
- Shipping to XYZJHB
World Courier
Internal Drivers
ABC Central Routine Lab
- Urine SDA GC/CT
- HIV Western Blot
XYZ JHB
XYZ Receiving Office
- Receive batches on Courier Tracking System
- Hand to laboratories for processing
XYZ Laboratory
- Processing Haematology and Chemistry
Runner
Hand delivered
JHB
Flow Cytometry
CD4
: JHB
Serology
Hepatitis B
Syphilis
JHB
PCR
HIV RNA PCR
Results
- PDF results are auto emailed to site.
- All hard copies print @ XYZ KZN

Proficiency Testing (EQA)

College of American Pathologists

DigitalPT AccuTest

Proficiency Testing (PT) is a means of evaluating a laboratory's performance through analysis of unknown samples provided by an external source.

American Proficiency Institute

40 YEARS OF QUALITY
1969 UK NEQAS 2009

NHLS Quality Assurance

EQA Summary Schedule

	A	B	C	D	E	F	G	H	I
1									
2								Investigation Report Required	
3									Accutest#
4		2009				Lab Name			CAP#:
5		Ship Date	EQA Provider	Survey Sequence	Module Code	Test Group Name	SMILE Reviewed (Date)	Site Response (Date)	Comment
6									
7	1	5-Jan	CAP	A	VM-1	Viral Markers	5-Mar-09	N/A	100% Successful
8	2	19-Jan	CAP	A	P	Parasitology	5-Mar-09	N/A	100% Successful
9	3	26-Jan	CAP	A	BP	Blood Parasites	1-Apr-09	8-May-09	Investigation required
10	4	26-Jan	CAP	A	FH3	Hematology w/Auto Diff and Photos	1-Apr-09	30-Apr-09	Investigation required for monocytes, neutrophils and blood cell ID.
11	5	9-Feb	CAP	A	E1	Limited Mycobacteriology	5-Jun-09	N/A	100% Successful
12	6	23-Feb	CAP	A	D5	Gram Stain	7-May-09	N/A	100% Successful
13	7	2-Mar	CAP	A	C3	General Chemistry	5-Jun-09	N/A	100% successful
14	8	16-Mar	CAP	A	CM	Clinical Microscopy	7-May-09	N/A	100% Successful
15	9	30-Mar	CAP	A	D4	Bacteriology	5-Jun-09	N/A	100% Successful
16	10	30-Mar	CAP	A	AHIV	Raphid HIV-1/2	5-Jun-09	N/A	100% Successful
17	11	13-Apr	CAP	A	G	Syphilis Serology	5-Jun-09	N/A	100% Successful
18	12	4-May	CAP	B	FH3	Hematology w/Auto Diff and Photos	9-Jul-09	6-Aug-09	Investigation for Cell ID
19	13	4-May	CAP	B	P	Parasitology	9-Jul-09	18-Aug-09	Investigation for Parasite ID and Photopages ID
20	14	11-May	CAP	B	VM-1	Viral Markers	9-Jul-09	NA	100% Successful
21	15	11-May	CAP	A	XU6	Serum HCG	5-Jun-09	N/A	100% Successful
22	16	18-May	CAP	B	BP	Blood Parasites	4-Aug-09	27-Aug-09	Investigation received for Blood Parasite ID, accepted
23	17	1-Jun	Accutest	2	BACT435	Bacteriology	11-Sep-09	N/A	100% Successful
24	18	1-Jun	Accutest	2	GRAM435	Gram Stain	11-Sep-09		Investigation required for gram stain.
25	19	1-Jun	Accutest	2	HEFD435	Hematology	4-Aug-09	N/A	100% Successful
26	20	1-Jun	Accutest	2	CELL435	Blood Cell ID	4-Aug-09	08/27/09	Investigation received, accepted
27	21	1-Jun	Accutest	2	SHCG435	Serum HCG	4-Aug-09	N/A	100% Successful
28	22	1-Jun	Accutest	2	BCHE435	Chemistry	4-Aug-09	N/A	100% Successful
29	23	1-Jun	Accutest	2	HIV435	Raphid HIV-1/2	4-Aug-09	N/A	100% Successful
30	24	1-Jun	Accutest	2	SYPH435	Syphilis Serology	4-Aug-09	N/A	100% Successful
31	25	1-Jun	CAP	B	C3	General Chemistry	4-Aug-09	N/A	100% Successful
32	26	6-Jul	CAP	B	D5	Gram Stain	11-Sep-09	N/A	100% Successful
33	27	3-Aug	CAP	B	CM	Clinical Microscopy			
34	28	3-Aug	CAP	B	E	Mycobacteriology			
35	29	10-Aug	CAP	B	XS4	Serum HCG			
36	30	10-Aug	CAP	B	AHIV	Raphid HIV-1/2			
37	31	10-Aug	CAP	B	D4	Bacteriology			
38	32	10-Aug	CAP	B	G	Syphilis Serology			
39	33	24-Aug	CAP	C	VM-1	Viral Markers			
40	34	14-Sep	CAP	B	F1	Fungal			
41	35	21-Sep	CAP	C	FH3	Hematology w/Auto Diff and Photos			
42	36	21-Sep	CAP	C	BP	Blood Parasites			

Protocol/Non Protocol Analytes: No Event or Not Ordered
Non-protocol Only: Result Not Submitted or Unable to Evaluate
Internal Investigation (INT) Recommended
Investigation Report Required (<100% but ≥80%) due within 30
Investigation Report (IR) Required (<80%) due within 30 days
Non-protocol Analyte
ACC - Acceptable

Lab Name: XYZ Lab
CAP# :
Accutest#:

Survey		2007 A / 1	2007 B / 2	2007 C / 3	2008 A / 1	2008 B / 2	2008 C / 3	2009 A / 1	2009 B	2009 2	2009 C / 3
Chemistry	ALT				100%	100%	100%	100%	100%	100%	
	Albumin				100%	100%	80%	100%	100%	100%	
Vitros 250	Alk Phos				100%	100%	100%	100%	100%	100%	
	AST				100%	100%	100%	100%	100%	100%	
	Bili, Direct				100%	100%	100%	100%	100%	100%	
	Bili, Total				100%	100%	100%	100%	100%	100%	
	Calcium				100%	100%	100%	100%	100%	100%	
	Potassium - K				100%	100%	100%	100%	100%	100%	
	Total Protein				100%	100%	100%	100%	100%	100%	
	Sodium - Na				100%	60%	100%	100%	100%	100%	
	Phosphorus				100%	100%	100%	100%	100%	100%	
Hematology	WBC	100%	100%	100%			100%	100%	100%	100%	
	RBC	100%	100%	100%			100%	100%	100%	100%	
CellDyn3200	Hgb	100%	100%	100%			100%	100%	100%	100%	
	Hct	100%	100%	100%			100%	100%	100%	100%	
Primary Instrument	MCV	100%	100%	100%			100%	100%	100%	100%	
	RDW	100%	100%	100%			80%	100%	100%	100%	
	Platelet	100%	100%	100%			60%	100%	100%	100%	
	Neutrophil	100%	100%	100%			100%	80%	100%	100%	
	Lymphs	100%	100%	100%			100%	100%	100%	100%	
	Eos	80%	100%	100%			100%	100%	100%	100%	
	Basos	100%	100%	100%			100%	100%	100%	100%	
	Mono	100%	100%	100%			100%	80%	100%	100%	
	Blood Cell ID				100%	78%	90%	90%	90%	80%	
Syphilis	MHA-TP	100%	100%	100%	100%	100%	100%	100%		100%	
	RPR	100%	100%	80%	100%	100%	100%	100%		100%	
	RPR Titer	100%	100%	80%	60%	100%	80%	100%			
GC-Chlamydia	Chlamydia	TNP	33%	66%							
	GC	TNP	0%	100%							
HCG	Serum hCG (S)	100%	100%	100%		100%					
	Serum hCG (XS-4)					100%	100%	100%		100%	
Anti-HIV	Method 1 (Abbott)	100%	100%	100%	100%	100%	100%	100%		100%	
	Method 2 (Trinity)	100%	100%	40%	100%	100%	100%	100%		100%	
Viral Markers	HBsAg	100%	100%	100%	40%	100%	100%	100%	100%		
	HBsAg Neutralz	100%	100%	100%	40%	100%	100%	100%	100%		

2009 Survey Schedule | **Result Summary** | LN Result Summary

Ready

EQA Review

SMILE – EQA Evaluation

Date: 12 July 2011	EQA Provider: CAP#
Site:	Panel: Clinical Microscopy, C-B 2011

Summary:
This EQA event was successful for all protocol analytes except as noted below.

A table containing manually evaluated results can be found on the following page.

Investigation Reports are required for all **protocol analytes** scoring less than 100%. The analytes requiring investigation are:

- None

Internal investigations are recommended for non-protocol analytes scoring less than 100% and for any bias, shifts and/or trends identified below:

Bias noted
Positive: None
Negative: AST, Creatinine, Sodium

Shifts noted: NA

Trends noted: NA

Non-Protocol Analytes scoring less than 100%:

- Sodium

Manual Evaluation

EVALUATION
ORIGINAL

VM-C 2010 Viral Markers

Test Method	Specimen	Your Result	Intended Response	Your Grade
HIV-1 WB Proteins	VM1-27	NO MAJOR PROT DETECTED		[26]
	VM1-28	gp41 p17/18 p24 p31/32 p51/55 p65/66 gp120/160		[26]
	VM1-29	gp41 p17/18 p24 p31/32 p51/55 p65/66 gp120/160		[26]
	VM1-30	gp41 p17/18 p24 p31/32 p51/55 p65/66 gp120/160		[26]
	VM1-31	NO MAJOR PROT DETECTED		[26]

SMILE – Proficiency Evaluation

Date: 8 October 2010 Site:

Proficiency Provider: CAP #7 Panel: Viral Markers VM-C, 2010

Summary:
This EQA event was successful for all protocol analytes.

The table contains manually evaluated results.

SAMPLE #	HIV-1 Western Blot		GRADE	HIV-1 WB Proteins		GRADE
	YOUR LAB RESULT	PEER RESULT		YOUR LAB RESULT	PEER RESULT	
VM1-27	Negative	Negative	Acceptable	Not Detected	Not Detected	100%
VM1-28	Positive	Positive	Acceptable	gp41 p24 p31/32 p51/55 p65/66 gp120/160	gp41 p24 p31/32 p51/55 p65/66 gp120/160	100%
VM1-29	Positive	Positive	Acceptable	gp41 p24 p31/32 p51/55 p65/66 gp120/160	gp41 p24 p31/32 p51/55 p65/66 gp120/160	100%
VM1-30	Positive	Positive	Acceptable	gp41 p24 p31/32 p51/55 p65/66 gp120/160	gp41 p24 p31/32 p51/55 p65/66 gp120/160	100%
VM1-31	Negative	Negative	Acceptable	Not Detected	Not Detected	100%
					Average	100%

Investigation Reports are required for all **protocol analytes** scoring less than 100%.
The analytes requiring investigation are:

- None

Summary:

This EQA event was successful for all protocol analytes except as noted below. Since no method was chosen CAP did not grade the survey. SMILE manually graded the survey; see survey for results.

The table contains manually evaluated results.

SAMPLE #	YOUR LAB RESULT	PEER RESULT	GRADE
CMMP-31	Sperm present	Sperm present	Acceptable

Investigation Reports are required for all **protocol analytes** scoring less than 100%. The analytes requiring investigation are:

- None

Internal investigations are recommended for the following non-protocol analytes scoring less than 100%:

- pH-33%
- Urobilinogen – 66%

Comments:

Congratulations on your good EQA results.

Internal investigation is suggested for the pH and urobilinogen analytes.

On future surveys please enter the method code so CAP can grade the survey.

If you have any questions about your review please contact me.

Please remember to include both the method (Siemens) and instrument (Visual) on the next survey so CAP can grade this survey.

On the CAP instructions it specifies that when resulting of secondary confirmation methods (MHA-TP) where your process is to confirm only weakly reactive or reactive specimens **that leaving presumed nonreactive specimens blank will results in a penalty. Please enter a code for your non-reactive test on your confirmatory test in the future.**

SMILE Investigation Form

SMILE –Investigation Form

Date: 12-Jan-09 Site:

Proficiency Provider & Panel: CAP C-C 2008

Test Analyte (One/form if problems are unrelated):	Reported Result:	Acceptable Result:	Previous Survey Problems:
Albumin	4.3	3.3 – 4.2	No

Laboratory Investigation: *(Attach supporting documentation. Please add detailed comments. Comment section will expand as needed.)*

1. Survey report examined for discrepancies, clerical errors and appropriate codes?
Comments: NA

2. Survey material receiving temperature, handling, reconstitution, storage and analysis investigated?
Comments: Received warm

3. Method & instrument history reviewed (Daily preventative maintenance performed? Reagents –open date, expiration date, number of tests left on the reagent, instrument settings, etc.)?
Comments: Yes

4. Quality Control reviewed (Circle or mark appropriate answer below.)? Yes

Mean established by? parallel testing or manufacturer's used QC ranges are set? Manufacture's range or locally established

QC within +/- 2 SD on day of survey? Yes No Number of levels of QC run? 2 3

What QC rules do you use? 1_3S Does your laboratory track Coefficient of Variation (CV) for analytes? CV = SD/Mean x 100 No

Comments: QC was within limits (slightly on the high side) but there was a humidity issue that has been resolved since

Root cause analysis

SMILE –Investigation Form

9. Personnel competency reviewed? Conduct staff education or retraining if applicable.
Comments: NA

10. Assess patient results for adverse impact? Review impacted patient results, amend results and notify physicians, if applicable.
Comments: The Vitros 250 weren't used yet to assay patient results

Deficiency Classification:

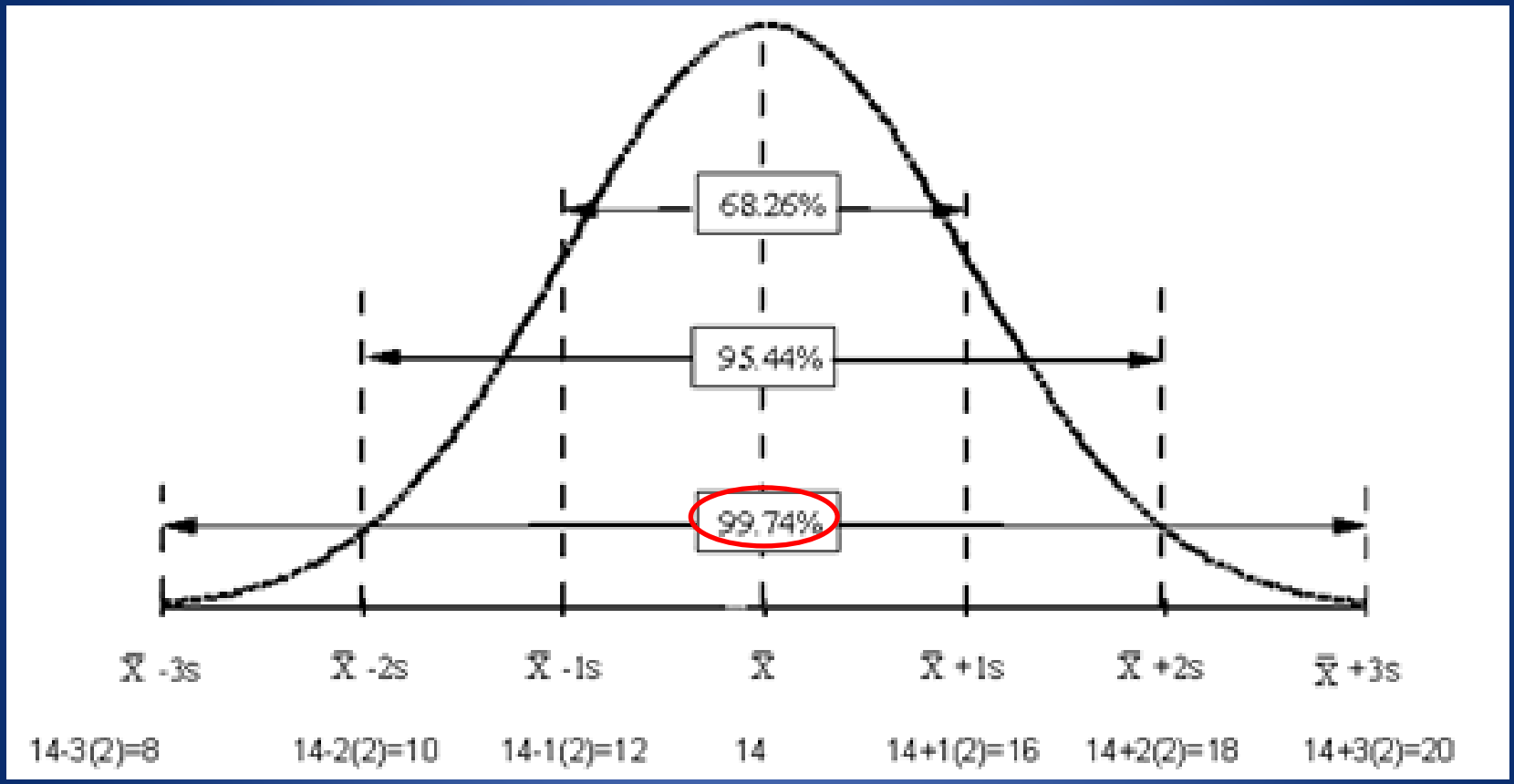
- [ ] Methodological
- [X] Technical
- [ ] Clerical
- [ ] Survey evaluation problem
- [ ] Other (explain)

Summary of Actions: Briefly discuss what actions were taken in this investigation and what you believe is the primary cause of this EQA problem.
The problem was caused by an influx of humidity in the slide reagent chamber due to screws that were not secured tightly enough

Summary of Actions: Briefly discuss what has been done to prevent this problem from occurring in the future.
The problem was fixed and now the) biomedical engineers will use this as a lesson in case similar a problem in the future

Prepared by:

Name/Title: , Lab QA Manager Date: 14-Jan-09 Signature: MAG


68.26%
95.44%
99.74%
$\bar{x}$ -3s
$\bar{x}$ -2s
$\bar{x}$ -1s
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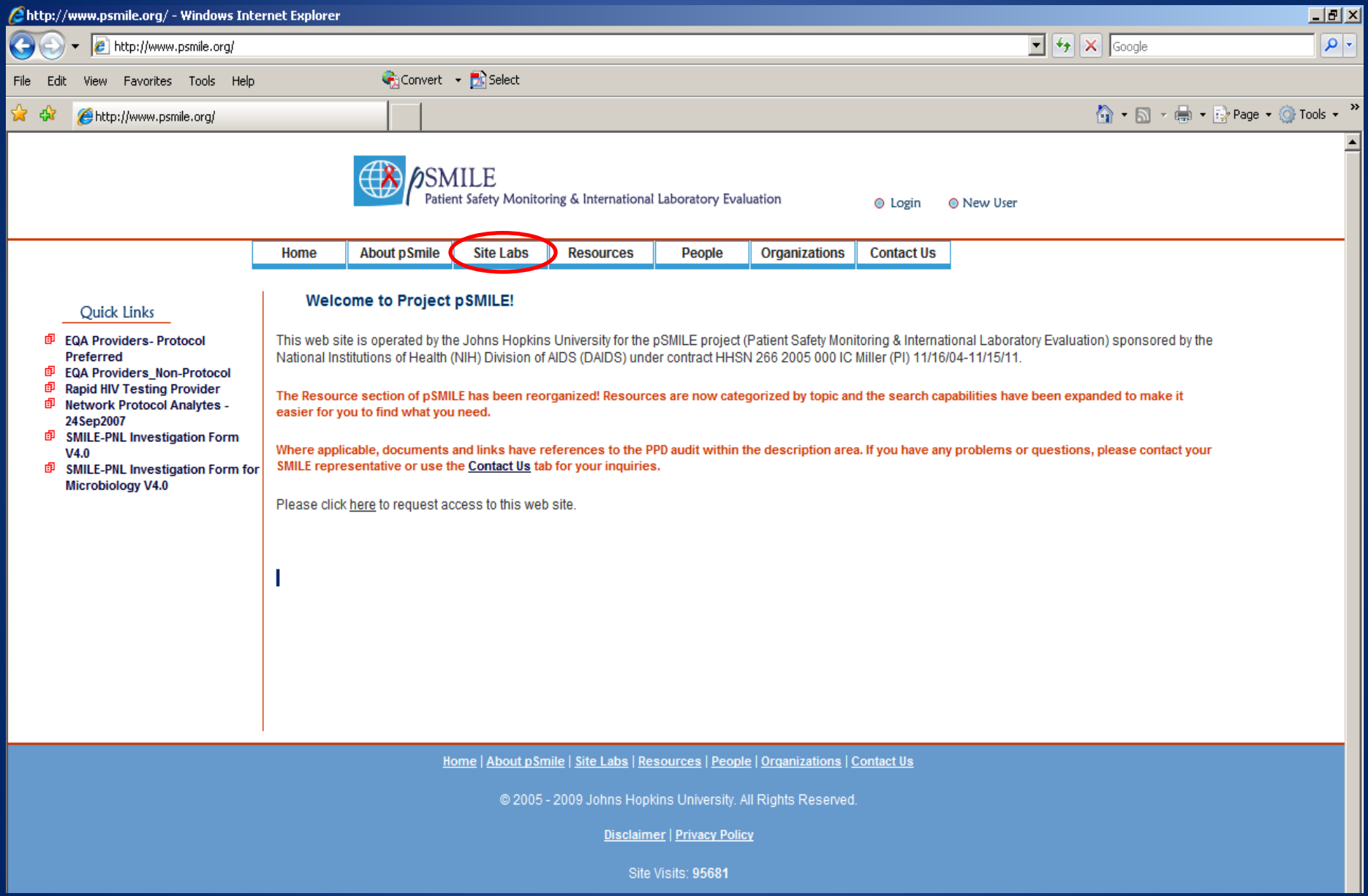
$\bar{x}$ +1s
$\bar{x}$ +2s
$\bar{x}$ +3s
14-3(2)=8
14-2(2)=10
14-1(2)=12
14
14+1(2)=16
14+2(2)=18
14+3(2)=20

Document Repository

EQA surveys, reviews and investigations on **www.psmile.org**

- Available to site labs (privately by log-in)
- Available to DAIDS and the Networks

Where do we store all of this documentation?



pSMILE
Patient Safety Monitoring & International Laboratory Evaluation

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Hello, asholan

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Quick Links

- EQA Providers- Protocol Preferred
- EQA Providers_Non-Protocol
- Rapid HIV Testing Provider
- Network Protocol Analytes - 24Sep2007 ▲
- SMILE-PNL Investigation Form V4.0 ▲
- SMILE-PNL Investigation Form for Microbiology V4.0 ▲
- Laboratory Mnemonic List ▲
- SMILE Laboratory Oversight List ▲
- SMILE Weekly EQA Review Schedule ▲

Documents 2009

Group - All sites

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Select Year 2005 2006 2007 2008 2009

Proficiency Testing Records

Instituto Dermatologico Y Cirugia de Piel(Dominican Republic)

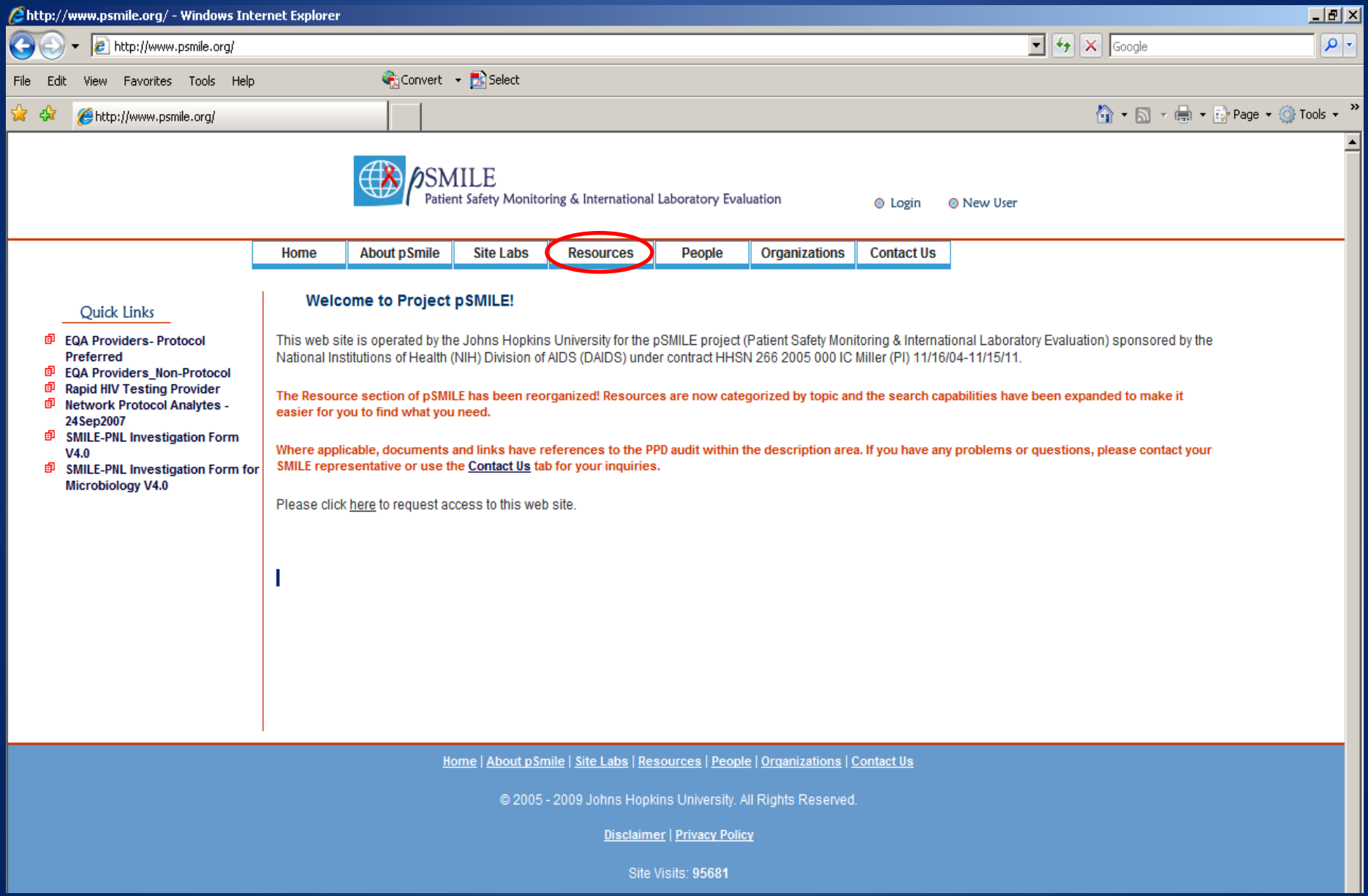
IDCP EQA Summary	10/05/2009	[Update]
IDCP CAP2009 Clinical Microscopy CM-B Review	10/04/2009	[Update]
IDCP CAP2009 Clinical Microscopy CM-B Survey	10/03/2009	[Update]
IDCP CAP2009 Chemistry C-B Review	08/04/2009	[Update]
IDCP CAP2009 Chemistry C-B Survey	08/03/2009	[Update]
IDCP CAP2009 Viral Markers VM-B Review	08/02/2009	[Update]
IDCP CAP2009 Viral Markers VM-B Survey	08/01/2009	[Update]
IDCP CAP2009 Hematology FH3-B Investigation	06/28/2009	[Update]
IDCP CAP2009 Hematology FH3-B Review	06/28/2009	[Update]
IDCP CAP2009 Hematology FH3-B Survey	06/27/2009	[Update]
IDCP CAP2009 Chemistry C-A Review	05/30/2009	[Update]

Document Repository

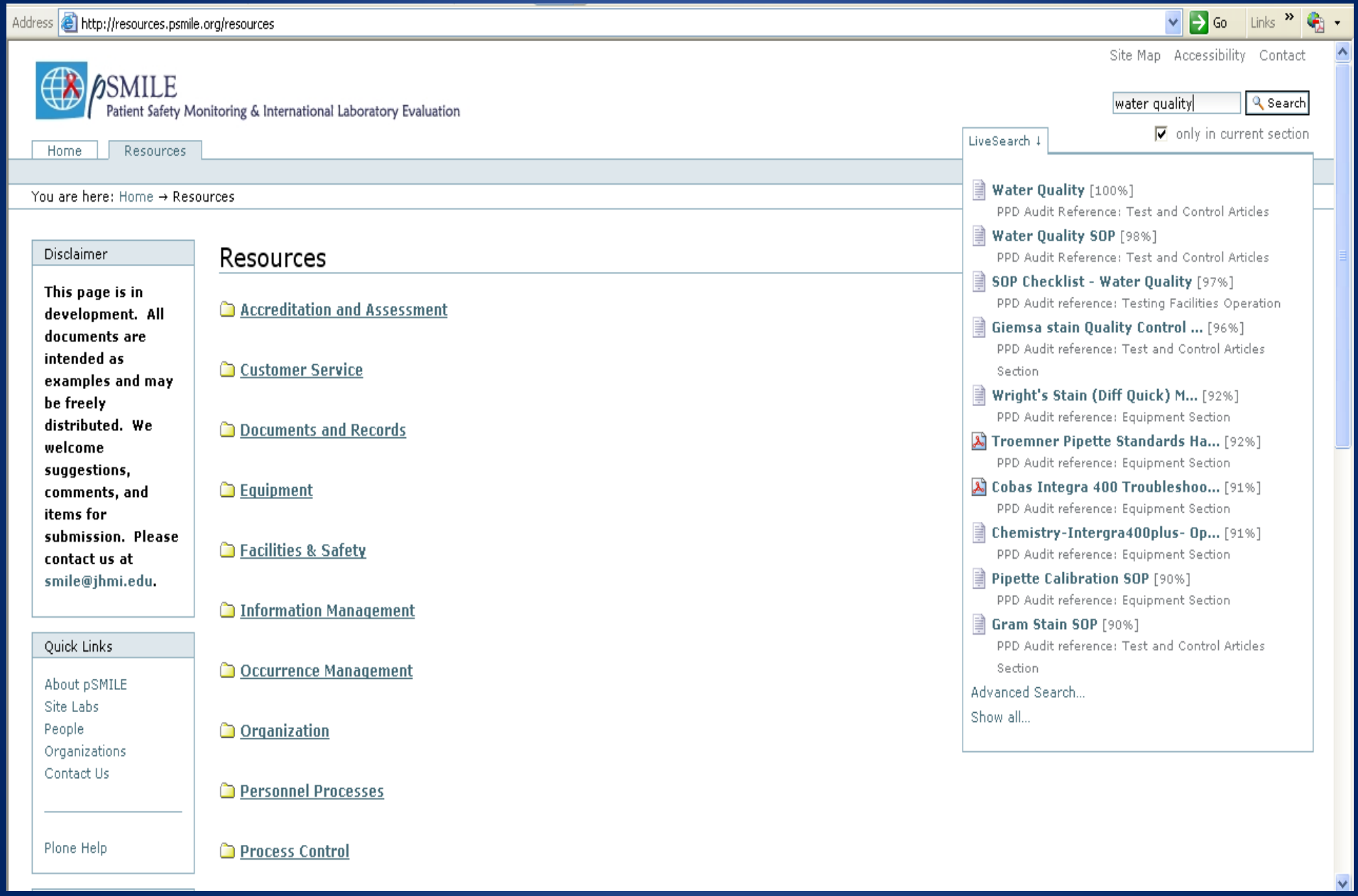
Also on **www.psmile.org:**

- Audits (DAIDS and PPD)
- Action Plans
- Protocols and Protocol Analyte Lists (PAL)
- Multitudes of other resources

Looking for example SOPs or other documentation?



Resources on pSMILE.org



MTS - Home Page - Windows Internet Explorer

http://www.medtraining.org/corpsite/

standard deviation diagram

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MTS Medical Training Solutions

UNIVERSITY OF WASHINGTON Department of Lab Medicine

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Major Functions of SMILE

- Action Plans
- Validation Review
- Protocol Analyte Lists
- EQA Review
- Investigations
- Resources/Training

QUESTIONS?

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