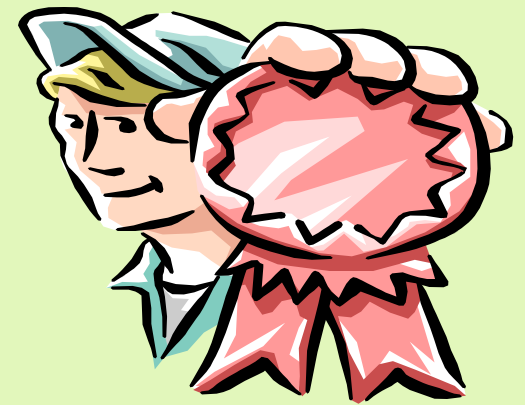




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Pilot Run of Drug Proficiency Testing Program (DPTP)

DOH - NRL / PIPAC



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Objective :

To present an overview
of Drug Proficiency Test
Program to participating
SDTL

- Objectives of PT
- Principles / benefits of PT
- Organization / process of PT



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What is a Proficiency test ?

The external assessment of a laboratory's performance using samples of known , but undisclosed content , and including comparison against other laboratories



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What is Proficiency Test ?

- AKA : External Quality Assessment

Survey (EQAS)

- System of objectively assessing the laboratory's performance by an outside agency (NRL)
- Establish inter-laboratory comparability, ensuring reliability of procedures , results and quality of product



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Background: DPT Program

➤ RA 9165

● Sec. 36 : Authorized drug testing

“ DOH is responsible for setting the standards and guidelines of operations, as well as **monitoring** of its implementation ”

● Sec 39

“ DOH is tasked to assure the **capacity, competence, integrity, and stability** in the conduct of examination



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Background: DPT Program

➤ IRR, Sec. 6.16: Proficiency Testing

- NRL shall conduct PT of both SDTL and CDTL
- Requirement for accreditation
- Failure to pass PT twice (2x) shall be basis of suspension of accreditation



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Background: DPT Program

MOA between DOH & PIPAC (Philippine Institute of Pure and Applied Chemistry) re conduct of PT ; July 23, 2003

- ISO accredited laboratory, participating in local and international PT program
- WHO recognized National Pharmaceutical Quality Control Laboratory



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➤ MOA between DOH & PIPAC

- DOH thru NRL shall conduct PT program
- PIPAC shall assist DOH - NRL in the design , implementation and evaluation of PT program



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Why the need for a PT ?

1. Regulatory reasons

- As an accreditation requirement
- As an external quality system tool to monitor and evaluate lab performance (worth of accreditation)
- As a monitoring tool of how standards / program outcomes are implemented



Why the need for a PT ?

2. Establish inter-laboratory comparability
3. Build positive values, enhance confidence and credibility among DTLs



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Why the need for a PT ?

4. Improve reliability of future testing, results → reduce legal risks
5. Stimulate performance improvements and promote high standards of practice



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Why the need for a PT ?

6. Identify problems/ errors

in the laboratory and
initiate remedial actions

7. Facilitate information
exchange , education thru
reports of PT outcome



Why the need for a PT ?

8. A device for improving project management

- Feedback on DT program
- Informed decisions
- Setting priorities for strategic planning
- Training assessment tools



Why the need for a PT ?

9. Technical reasons

- Determine performance characteristics of test methods/kits
- Enhances reliability of results , quality of product



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Who benefits from the PT ?

1. Laboratory

- Feedbacks for improvement
- Maintenance of accreditation status
- Objective evidence of quality
- Identification of training needs

2. Client / public

- Identifies quality, reliable DTLs



Who are the beneficiaries ?

3. Accreditation / regulatory agencies (BHFS, BFAD)

- Establishes worth of accreditation
- Provides info on standard setting
- Provides basis for policy statements



DPT Program : highlights

- Collaborative activity with PIPAC
- PT “Pilot testing” : 100 labs
 - random selected private SDTL
 - All Government SDTL
- Funds : Government -DOH
WHO funded project



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PT highlights

Organizational design system, processes patterned after :

- **ISO Guide 43-1** : Proficiency testing by inter-laboratory comparisons
- **PNS 1605**: Phil standard for PT
- **ILAC –G132000** : Guidelines for the requirements for the competence of providers of PT schemes



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DPT Program : highlights

- 10 test samples are given to the participating SDTL's
- SDTL's shall test the samples under same laboratory conditions
- Anonymity of participating laboratory



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DPT program : highlights

- For the pilot run → NO FEES will be collected
- Results are submitted thru internet via DTOMIS/ PT and linked to PIPAC website
- Hard copy of result thru mail



DPT program : highlights

- Demographic data, statistical tools chosen to reflect objectives and desired information
- Initially will use THC/ Meth samples



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PT process

NRL –PIPAC

SDTL

Prepare QA spec



Examine spec

Analyze results



Report results

Prepare reports



Evaluate



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PT process: stages

1. Preparation of PT design
2. Preparation of unknown panel(10)
3. Random selection of participating SDTL
4. Unknown panel distribution
5. Testing of unknown panels by SDTL



PT process: stages

6. Submission of PT results via DTOMIS ASAP and within 48 hrs via mail or fax
7. Data collection , statistical analysis
8. Final evaluation report submitted to SDTL by NRL within 8 weeks



Unknown Specimen Panels

- Specimen matrix are synthetic urine with known concentrations of metabolites simulating human urine
- Some contain Meth /THC with established but undisclosed varying concentration
- Some may have negative urine



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What are the roles of participating SDTL ?

1. Pick up the unknown specimen panels from NRL-EAMC from Sept 28,29,30
 - ✓ Fill out acknowledgement receipt form completely and accurately
 - ✓ Ensure personnel who picks up specimen are competent and reliable
 - ✓ Inspects specimen upon receipt and enters appropriate description



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What are the roles of participating SDTL ?

2. Ensure specimen are transported properly from pick up point to laboratory site

- ✓ Transport specimen in " cold chain "
 - styro or coleman packed with ice
- ✓ wrap entire specimen panel in plastic to prevent getting soaked
- ✓ prevent exposure to direct sunlight
- ✓ no delays in transport of specimen



What are the roles of participating SDTL ?

3. Analyze all 10 unknown specimen samples

- ✓ Submit results on line via DTOMIS within 48 and hard copy via mail to NRL-EAMC
- ✓ Fill up PT result form completely



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- In the future , service fees for Proficiency Testing shall be assessed to participating DTL's.



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PT principles

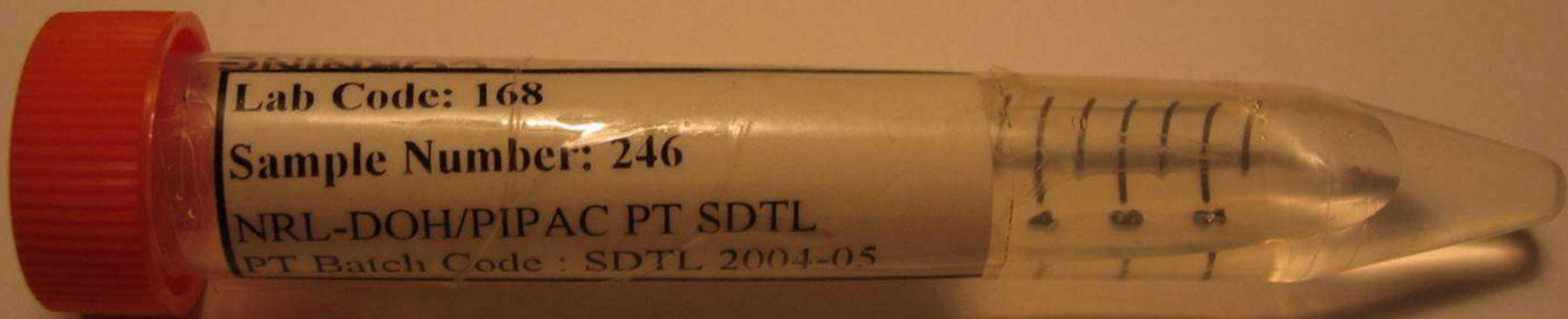
- Confidentiality of individual reports
- Avoiding provocative statements
- Identify unsatisfactory performers in groups / individuals to identify trends
- Providing educational opportunities
- PT provider acts as an adviser , rather than enforcer



Laboratory Code 001

IMPORTANT: To the participating laboratory: Please read Instructions and fill out Page 1 (Information as packaged is opened and sample are checked.)

Sample No: 1171	Sample No: 452	Sample No: 396	Sample No: 956
Sample No: 134	Sample No: 2045	Sample No: 1442	Sample No: 1575



Lab Code: 168

Sample Number: 246

NRL-DOH/PIPAC PT SDTL

PT Batch Code : SDTL 2004-05



Thank You for your support



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