

**5<sup>th</sup> HEPATITIS C**  
TECHNICAL ADVISORY  
GROUP  
**TAG Meeting**

# **BLOOD BANK SCREENING QUALITY ASSURANCE: CURRENT PRACTICES AND FUTURE DIRECTIONS**

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# Outlines

- Quality assurance
- Criteria for inclusion
- EQA testing at LC
- Results
- Challenges
- Future directions

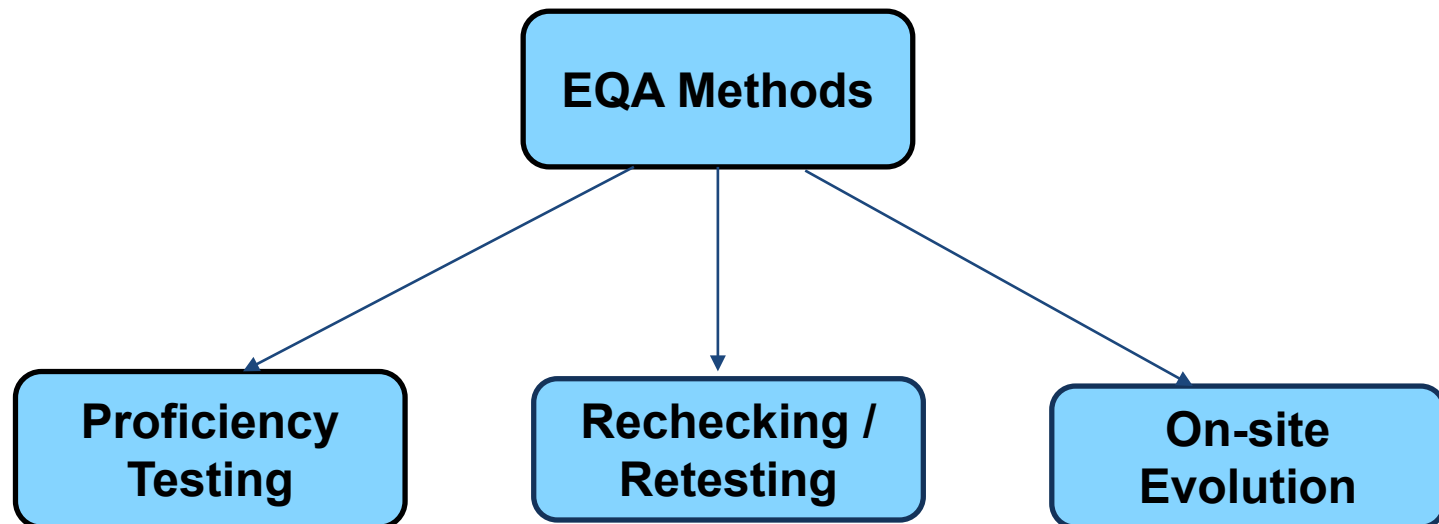
# Quality assurance

- Quality systems are crucial for the overall effectiveness of all aspects of the screening programme and in assuring the quality, safety and efficacy of all blood and blood products



# External quality assessment

- Assessment is a critical aspect of laboratory quality management, and it can be conducted in several ways



# State Blood Safety Program



- Since 2019 - 16 out of 21 Blood Banks participate in the State Blood Safety Program

# Criteria for inclusion in the State Blood Safety Program

- ✓ Possession of a license
- ✓ Required testing methods for HIV, HBV, HCV by EIA;
  - ✓ For Syphilis by TPHA, EIA or RPR
- ✓  $\geq 1700$  donations per year;
- ✓ Annual 10% increase of unpaid donation
- ✓ At least 1000 donations unpaid donation per year (30% repeat donations)
- ✓ Provide HCV screening positive samples to Lugar center for HCVcoreAg confirmation

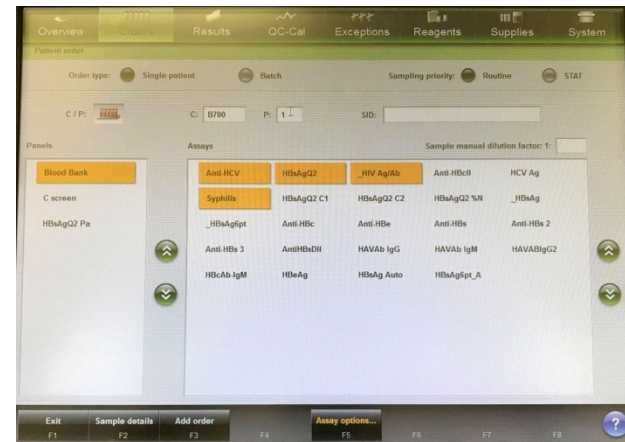
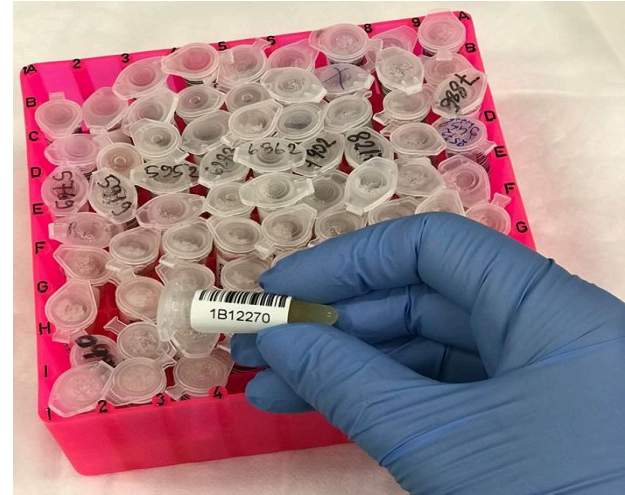


# State Blood Safety Program requirements

- 2011 - All Blood Banks, involved in the State Blood Safety Program are required to participate in the EQA
  - Aliquots from 5% of all donations are randomly selected from each Blood Bank enrolled in the State Program and rechecked by Lugar Center as part of EQA
- Since 2015, all Blood Banks, participating in the State Blood Safety Program, are required to perform international provider's Proficiency Testing (PT) quarterly

# EQA confirmatory testing at Lugar Center

- Lugar Center provides regular EQA confirmatory testing for blood banks twice in a year;
- At Lugar Center samples are registered, re-labeled and rechecked using Chemiluminescent microparticle immunoassay (CMIA) for HIV, HCV, HBV and Syphilis
- Discrepancies are confirmed by:
  - HIV, HCV, Syphilis - Line Immunoassay
  - HBs Ag – HBs Ag confirmatory (CMIA)



# Retesting results of 2018 samples

In total 2937 aliquots were received from different Blood Banks participating in the state program

Confirmatory testing period	# of participating banks	# of samples	all types of discrepancy
2018 1 <sup>st</sup> 6 month	14 (15-1)	1444 (1480-36)	18 (1.2%)
2018 2 <sup>nd</sup> 6 month	15	1493	19 (1.3%)

# Discrepancies of 2018 samples

Discrepancies	1st 6 month # / %	2nd 6 month # / %
Testing results discrepancies between LC and the BBs	18 / 1.2	18 / 1.3
Inappropriate storage and shipping (spilled samples)	36 / 2.4	0
Mislabeled	0	1 / 0.06
Concordance	1326 / 99	1460 / 98.7

Newly collected samples are requested from donors with discrepancies samples

# Challenges

- Lack of standardized testing, technologies and SOPs
- No EQA are established for the Blood Banks not participating in the State Blood Safety Program.
  - Impacts quality patient care

# Future directions

- Help in developing standards and guidelines for technologies and testing strategies
- Preparation, packaging and distribution of panel samples
  - Receiving, analyzing results and preparing evaluation reports
  - Provide necessary feedback, recommendations
- Involve all banks in EQA, who are not participating in state programs

# Acknowledgements

- NCDC Lugar Center laboratory team - for testing and data analysis
- Blood Banks participating in the State Blood Safety Program



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