MINISTRY OF HEALTH
SINGAPORE

Stakeholder Consultation for Clinical Laboratory Services under the Healthcare Services Act

Presented by Health Regulation Group
Ministry of Health
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Agenda

Introduction

- Under the Healthcare Services Act (HCSA), regulations are structured into **General Regulations, Advertisement Regulations** and **Service-specific Regulations**
  - **General Regulations and Advertisement Regulations**: General requirements broadly applicable to **all licensees**
  - **Service-specific Regulations**: Unique requirements contextualised to each service or stipulates specific requirements articulated in the General Regulations

- From Sep 2021, Clinical Laboratory Service licensees must comply with
  i. **General Regulations**,
  ii. **Advertisement Regulations**, and
  iii. **Clinical Laboratory Service Regulations**

- Licensees providing Nuclear Medicine Assay Service must additionally comply with
  iv. **Nuclear Medicine Assay Service Regulations**

Introduction

- This presentation gives an overview of the **service requirements** that will apply to Clinical Laboratory Service licensees under HCSA
  - Most of the requirements have been ported over from the requirements under **PHMC Regulations 47 to 56**
  - Technical requirements (e.g. specific requirements on laboratory safety or specific clinical laboratory disciplines) will be stipulated in the **Licensing Terms and Conditions (LTCs)**
  - Illustrations of good practices to help licensees interpret and meet the outcome-based approach will be carried in an **Explanatory Guidance**

Most of the PHMCR requirements will be enhanced for greater governance and regulatory clarity

A. Licensing matters

1. Service modalities provided under licence
2. Notice to add new service modality

B. Governance and personnel

3. Skills and competencies of Clinical Governance Officer
4. Duties and responsibilities of Clinical Governance Officer
5. Staff involved in provision of clinical laboratory service

C. Facilities and equipment

D. Service provision

6. Provision of clinical laboratory service to patients
7. **[NEW]** Handling of specimens
8. **[NEW]** Acceptance and rejection of specimens
9. **[NEW]** Testing of specimens
10. Clinical laboratory report
11. **[NEW]** Price transparency
12. Outsourcing of tests

E. Systems and Committees

13. Quality Management System
14. Laboratory safety requirements

F. Keeping of records

Definition of “Clinical Laboratory Service”

“Clinical laboratory service” means the examination or testing of any matter derived from the body of any individual for the purpose of —

(a) assessing the health, condition or genetic predisposition of that individual or any other individual;

(b) predicting or providing a prognosis of the health or medical condition of that individual or any other individual;

(c) diagnosing a disease, disability or condition or an injury of the body or mind of that individual or any other individual;

(d) determining the intervention to be taken, or the effect of any intervention taken, of a disease, disability or condition or an injury of the body or mind of an individual;

(e) ascertaining the cause of death of that individual or any other individual, or the result of a medical or surgical treatment given to that individual or any other individual; or

(f) assessing the health, condition or suitability of any human biological material that is used, or is intended to be used, in relation to any healthcare service;

Source: First Schedule HCSA

A. Licensing Matters

Licensing Matters

Service modalities provided under licence and notice to add new service modality

- **Licensees must notify MOH of every lab discipline and specified test that they intend to provide**
  - During licence application and renewal – **no later than 2 months before** intended commencement date and licence expiry respectively (under Regulation 4 of the General Regulations)
  - Additional lab disciplines and specified tests after licence application / between renewals – **no later than 1 month before** date of provision
    - Licensees should not commence with provision of the additional modality until the modality is reflected on the licence.

Lab disciplines

a) Anatomic pathology
b) Chemical pathology
c) **[NEW]** Clinical toxicology
d) Cytogenetics
e) **[NEW]** Cytology
f) **[NEW]** Genetic or genomic testing
g) Haematology
h) Histocompatibility
i) Immunology
j) Medical microbiology
k) **[NEW]** Molecular pathology
l) Transfusion medicine
m) Any other discipline acceptable to DMS

Specified tests

a) Human Immunodeficiency (HIV) Screening
b) HIV Confirmation
c) Pre-implantation Genetic Testing for Monogenic / Single Gene Defects (PGT-M)
d) Pre-implantation Genetic Testing for Chromosomal Structural Rearrangements (PGT-SR)

Tests required under National Proficiency Testing Schemes

a) Acid-fast Bacilli Smear Test
b) **[NEW]** Glycated Haemoglobin (Haemoglobin A1c)

Tests which no longer need to seek prior approval from MOH before commencement

a) Blood Group (ABO) and Rhesus (*D*) Type tests
b) Malaria Parasite test
c) Legionella test

B. Governance and Personnel

Enhanced Governance

Overview of governance roles required under HCSA

Personnel	Responsibilities	Who can be appointed
Licensee	The licensee is **responsible and accountable for overall compliance** with HCSA.	Licensee can be a corporation (e.g. the company that owns the Clinical Laboratory Service) or an individual (e.g. CEO of the company). Implication to be considered: the licensee is liable and responsible for non-compliance found/reported (e.g. fined).
Key Appointment Holders	Responsible for the **strategic leadership and general management oversight** of the licensable service.	E.g. Board of Directors (of the corporate entity or of the owner of a subsidiary).
Principal Officer	**Oversees day-to-day management** of the licensee and ensures operational compliance with HCSA.	E.g. CEO or COO for larger set-ups, or individual previously appointed as Lab Manager under PHMC Reg 49 for smaller set-ups.
Clinical Governance Officer	Responsible for **clinical and technical oversight and implementation** of complex services that require specialised expertise.	E.g. individual previously appointed as Lab Licensee under PHMC Reg 47.
Section Leader	Provides **oversight on the day-to-day laboratory activities on the ground** and **direct supervision to all staff with less than 2 years of relevant experience for the service modality**	E.g. individual previously appointed as Trained Person under PHMC Reg 50. At least 5 years' relevant work experience required.

[ENHANCED] Skills and competencies of Clinical Governance Officer (CGO)

To provide clinical and technical oversight of technical and complex services by a qualified person

CGO is required for Clinical Laboratory Service under HCS (General) Regulation 11

- Similar to the lab licensee requirements under PHMC Regulations 47-48

CGO Requirement
A locally registered pathologist who has the relevant higher qualification and training in the clinical laboratory discipline that the licensee provides, **OR**
A person who has a 1) degree in medicine **AND** 2) relevant qualification or certification in pathology awarded by a professional board that is acceptable to DMS (e.g. American Board Certification, MRCPath, (FRCPath), FRCPA, AACB, ABMM, DABCC, Chartered Scientists (CSci)) **AND** 3) minimum of 5 years' qualifying working experience in a clinical laboratory acceptable to DMS and relevant to the scope of services under the oversight of the CGO

[ENHANCED] Skills and competencies of Clinical Governance Officer (CGO)

To provide clinical and technical oversight of technical and complex services by a qualified person

Under exceptional circumstances, DMS's approval may be granted to an individual who may not meet the CGO requirement, based on the following principles:

1. Nature of lab discipline / test provided
2. Patient safety risk
3. Holistic assessment on lab's scope of services
4. Relevance of the individual's qualifications, training and experience in fulfilling the duties and responsibilities of a CGO with regard to the lab's scope of services
5. Minimum years of qualifying working experience (at least 5 years required)

There must be sufficient number of CGO(s) to cover the scope of services provided (e.g. lab disciplines, fields or specialised tests)

- Under HCSA, more than one CGO is allowed to be appointed for the same licence
- However, depending on each CGO's qualifications, experience, capacity and bandwidth, he/she may be able to provide oversight for more than one lab discipline and/or specified test

[ENHANCED] Duties and responsibilities of the CGO

The CGO has the following broad duties and responsibilities:

a) assisting the licensee in promoting safe, ethical and appropriate practices in the provision of the clinical laboratory service

b) setting and implementing appropriate policies of the licensee for the safe and ethical provision of the clinical laboratory service

[ENHANCED] Duties and responsibilities of the CGO

Specifically, the CGO is responsible for —

a) Providing **clinical governance and technical oversight** of the service, including overseeing and implementing policies, processes and programmes;

b) Providing **day-to-day technical management** of the service and ensuring compliance to the various rules and regulations;

c) Ensuring the **implementation and regular review of systems** for clinical governance, risk management and effective quality management in order to detect and address, in a timely manner, any risks affecting the safety and welfare of, and the continuity of care provided to, patients.

d) Ensuring that any **weakness or inadequacy in the provision of the service is promptly addressed and remedied**;

e) Evaluating every new test or test method before its implementation;

f) Establishing and implementing policies and procedures relating to technical and clinical standards for **compliance by the staff**, and ensuring that the staff comply with them;

g) Ensuring that there is **close supervision and continuous competency assessment** of the staff in the performance of their work;

h) Ensuring that the staff are provided with continuing clinical laboratory **training** that is adequate for the staff to acquire and maintain the requisite skills and competencies to perform their work and the relevant knowledge to ensure their safety when performing their work.

[ENHANCED] Staff involved in provision of clinical laboratory service [1/2]

To ensure staff providing care are qualified, competent and adequate

- Licensee must ensure that **the number and competency** of staff can support the service, **commensurate with the scale and complexity of the service**
  - E.g. licensee must employ an **adequate number of staff** to assist the licensee in providing the applicable service in a safe manner; **and**
  - ensure that every staff member has the **necessary professional registration (if applicable), qualifications and competencies** that are required for the work performed by that staff member consistent with the QMS
- There must at least one **Section Leader** appointed for each laboratory discipline and specified test, to provide governance oversight for day-to-day operations and supervise staff
  - The Section Leader must have **at least 5 years of work experience** relevant to the laboratory discipline and specified test
  - Similar to the CGO, each Section Leader's qualifications and experience may allow him/her to provide oversight for more than one lab discipline or specified test
- Staff with less than 2 years' relevant work experience must perform any task or provide any service **under the close supervision of either a CGO or a Section Leader**

[ENHANCED] Staff involved in provision of clinical laboratory service [2/2]

To ensure staff providing care are qualified, competent and adequate

- A licensee must ensure that every staff member —
  a) is adequately trained for the work performed by the staff member and attends regular training in accordance with a continuing training programme;
  b) has the relevant awareness and knowledge of, and attends regular training on, clinical laboratory safety measures; and
  c) is assessed periodically and before their independent performance on the staff member's competencies and work performance

C. Facilities and Equipment

[ENHANCED] Facilities and equipment

The premises and equipment are suitable, safe and adequate for the proper and efficient performance of service with accuracy, timeliness and safety

a) Adequate space to carry out services and adequately secured to prevent unauthorised access

b) All equipment are checked regularly and certified by relevant authority for safety and performance, and complies with the manufacturer's specifications or standards governing their use (e.g. chemical metrology standards set out by HSA for glucose testing)

c) All equipment, appliances and materials used must be properly maintained and checked to ensure that they operate normally and accurately at all times.

d) Storage space is adequate and secured, with effective measures put to prevent unauthorised access to and use of the reagents and specimens, and there is proper documentation for it

e) Adequate decontamination facilities and equipment

D. Service Provision

[ENHANCED] Provision of clinical laboratory service to patients

Ensuring clinical gatekeeping and appropriate follow-up for laboratory tests

- Licensee can conduct a clinical laboratory test for a patient **only if**
  a) the patient is **referred** to the licensee by a registered medical practitioner or dental practitioner, **and**
  b) the test is **prescribed** by the referring healthcare professional mentioned above

- Exception: Where a licensee provides clinical laboratory services to licensee(s) approved under the **Collaborative Prescribing framework** (e.g. the laboratory is part of the hospital, or in a contractual arrangement to provide lab services to the hospital), the licensee can also conduct clinical laboratory tests prescribed by a nurse or pharmacist credentialed as a Collaborative Prescribing Practitioner

- For **walk-in patients** without the above referral, the licensee must either
  a) **refer** them to a registered medical or dental practitioner, or
  b) Have a **medical or dental practitioner on-site** to review the patient's case and provide the patient with medical counselling on the implications of the test results (including abnormal results)
    i. If necessary, the licensee must refer the patient to another medical practitioner for follow-up medical advice or treatment, e.g. due to abnormal results

[NEW] Handling of specimens

Specimen should be properly packaged, labelled and handled to ensure integrity

- Licensee must ensure that every specimen received for testing is
  a) kept in packaging that is **durable, leak-proof and watertight**
  b) at all times **appropriately and accurately labelled** in accordance with documented protocols to ensure traceability to patient

- For specimens suspected to contain **infectious agents**, licensee must ensure that the specimen is kept in proper packaging, labelled, transported and handled in accordance with any written law that governs the handling or packaging of such an infectious agent (e.g. Biological Agents and Toxins Act)

- Licensees must ensure that specimens that are **transported** to another location are **properly labelled**
  – Label must contain a description of the **general nature** of the transported item (e.g. with a biohazard / radioactive sign, where applicable)

[NEW] Acceptance and rejection of specimens

To ensure the testing of specimens that meet the acceptance criteria

- Licensee must have **written policies and processes** to govern
  - Acceptance of specimens
  - Handling of rejected specimens

- The written policies and processes must include
  - **Clear criteria** for acceptance and rejection of specimens
    - The identifiers on the request form and specimen label must match
  - **Instructions for handling and documentation** of rejected specimens, including:
    - Rejected specimens are not returned to the requestor except in circumstances specified in the policies
    - Requestor must be informed of the rejection of the specimen

- Licensee must provide patients who wish to collect his/her own specimen with **proper instructions** on collection of the specimen

[NEW] Testing of specimens

To ensure that every test is of appropriate clinical utility and accuracy

- There must be **proper documentation of every test procedure undertaken**, including
  - Source or reference for the procedure (SOP of test procedure e.g. Instruction for Use of reagents, operating manual of equipment)
  - Date the procedure was last reviewed
  - Calibration standards and controls required
  - Instructions for handling of specimen and issuing the test results to the requestor
- There must be **regular evaluation of every reagent** to ensure that it is capable of consistently producing accurate results. Reagents must not be used after its expiry date.
- Result(s) of every test must be **confirmed or validated** by another test using internal quality control materials or other validation process (e.g. test carried out by another licensee through specimen exchange)
- There must be **documentation for criteria used for the acceptance of quality control** of testing and any results and actions to be taken when the quality control is unacceptable
- Every test result must be **reported and interpreted** on the basis of established norms and ranges
- The licensee must carry out an **investigation of every non-concordant test result** and take appropriate action to **address the discrepancy**

[ENHANCED] Clinical laboratory reports [1/2]

- **Licensee must issue a clinical laboratory report in written form (in print or digital) for every test conducted for a patient**

- **Clinical laboratory reports must contain the following information**
  a) business name & address/vehicle no. of the licensed premises/conveyance at which the test is conducted
  b) the patient's name and NRIC or passport number
  c) name of healthcare professional who requested the test
  d) date and time of collection of specimen by clinical laboratory
  e) type of specimen tested (e.g. urine, joint aspirate)
  f) for a tissue specimen, the anatomical site of the specimen
  g) date on which the clinical laboratory test is conducted
  h) test results and any other necessary information expected for the interpretation of results
  i) date and time the report is issued
  j) Signature (including e-signature) of CGO or suitably qualified designee (e.g. Section Leader for the laboratory discipline) reporting and interpreting the findings of the clinical laboratory test

- **For outsourced tests, the outsourcing licensee must retain a copy of the report by the testing laboratory**

- **Record retention must comply with national requirements (e.g. 2015 National Record Retention Guideline), or without which, the laboratory's documented policy**

[ENHANCED] Clinical laboratory reports [2/2]

- **Clinical laboratory reports must, without undue delay, be given to the healthcare professional who requested the test or another healthcare professional designated by the referring healthcare professional to receive the findings, and include all laboratory test findings (normal or otherwise)**
  - If necessary, urgent verbal reports may be given according to documented policy, and the name of the person providing and receiving the report and the date and time of communication must be documented
  - Results, if provided to patients directly, must only be given according to the laboratory's established policy
  - For results with potential to have a serious immediate impact on the patient's safety and well-being, and where the requesting or designated healthcare professional cannot be contacted in a timely manner, the clinical laboratory must make efforts to contact the healthcare institution
  - There must be documented procedures to ensure prompt reporting of patient results during downtime and recovery of the laboratory's information system

- Licensee must implement processes to identify and bring to the attention of the healthcare professional who ordered the examination any clinically significant **abnormal or incidental findings** in the clinical laboratory report

- If the licensee discovers any **error** in a clinical laboratory report after it is issued, the licensee must immediately notify the referring or designated healthcare professional of the error and issue an addendum to the report.

- If it is necessary for a copy or reproduction of the clinical laboratory report, the licensee must ensure that the report is **copied or reproduced in its entirety**

[NEW] Price transparency

Patients are provided with accurate information about charges for price transparency to make informed choices

- Base requirements are stipulated in HCSA General Regulations Section 32-34 Price Transparency (please refer to the consult materials for General Regulations).

- In addition, the following charges must be made available to any patient and requesting healthcare professional or the institution:
  - Every laboratory test provided to the patient to be tested
  - Any other laboratory test offered by the clinical laboratory upon request
  - Any relevant administrative fees

Outsourcing of tests

Accuracy and timeliness of test and result reporting should be ensured when outsourcing tests

- A clinical laboratory test can be outsourced to:
  a) Another clinical laboratory service licensee
  b) A clinical laboratory operating outside Singapore which is accredited or accredited to provide specific tests by an accreditation body approved by DMS
     a) The current list of approved accreditation bodies are being reviewed and will be updated on a regular basis

- Appeals to outsource tests to any other clinical laboratories will be assessed on a case-by-case basis

E. Systems and Committees

[ENHANCED] Quality Management System

To establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service

The licensee must **establish and implement a QMS** to provide for all the following:

a) Investigation of occurrence or compliant that discloses or may disclose weakness or inadequacy affecting the quality of the service;
b) Identification and implementation of appropriate and effective actions to address any weakness or inadequacy;
c) Auditing the provision of the service;
d) Implementing system for appropriate accountability, roles, responsibilities and continuing education programmes for quality management;
e) Implementing policies and procedures relating to risk management;
f) Identification of key performance indicators (KPIs) for assessing performance outcomes;
g) Implementing quality control measures for all equipment, and all specimens kept and tested;
h) Implementing systems and processes to ensure the prompt return of clinical laboratory findings;
i) Validation of all critical processes, and test methods and results;
j) Participating and performing satisfactorily in appropriate external quality assessment (EQA) programmes for all test;
k) Having reports for EQA programmes, investigations and discussions reviewed by the CGO or a suitably qualified designee;
l) Maintaining adequate and accurate documentation on QMS, including SOPs, work instructions, policies and procedures and quality control records.

The QMS must be reviewed at least annually for effectiveness, and updated periodically.

[ENHANCED] Laboratory safety requirements

Licensee must develop and implement appropriate and effective laboratory safety measures to prevent the occurrence of any adverse incident and reduce hazard

- The licensee must maintain **accurate and up-to-date written documentation** on the laboratory safety policies and processes and make them available to all the licensee's staff
- The licensee must ensure that the **staff comply** with the policies and processes
- The licensee must provide every staff with the required **personal protective equipment**
- The licensee must provide at every licensed premises an adequate number of **first-aid kits** for emergency use and that are readily accessible
- The licensee must ensure that every staff attends **regular training** on, and is adequately trained in, laboratory safety
- The licensee must implement a **chemical hygiene plan** that sets out the safety procedures for every chemical used at the licensed premises

F. Keeping of records

[ENHANCED] Keeping of records [1/2]

- The licensee must ensure that there is adequate and appropriate **documentation** of policies, processes and programmes, including to ensure proper document access and control.

- A licensee must maintain proper, complete and accurate records in respect of the following:

a) Specimen records

i. Patient's name and NRIC or passport number
ii. Name of person who referred the specimen for testing
iii. Name of person who collected the specimen (where applicable)

b) [NEW] Test records

i. Date, time, type and results of test conducted on specimen
ii. Name of person who conducted the test
iii. Result(s) of test
iv. Instrument raw data and laboratory worksheets

c) [ENHANCED] Quality records

i. QMS (slide 29)
ii. Quality management reviews
iii. Master list of personnel initials and signature
iv. Personnel job description, training and competency assessment
v. Review of policies and processes, and version read documentation
vi. Equipment and instrument maintenance and calibration
vii. Calibration and quality control
viii. Test evaluation
ix. Proficiency testing / external quality assurance programme performance

[ENHANCED] Keeping of records [2/2]

d) [NEW] Laboratory records

i. Patient's name and NRIC or passport number
ii. Patient's gender
iii. Date and time the specimen is taken from the patient (if available)
iv. Date and time of the receipt of the specimen by the licensee
v. The type of specimen
vi. For a tissue specimen, the anatomical site of the specimen
vii. The name of the person who took the specimen from the patient
  - Compulsory for blood grouping, crossmatching, tissue typing and genetic testing

viii. Relevant clinical status of the patient (where required), including whether the patient has fasted before the taking of the specimen;
ix. Characteristics of the specimen that may provide information that is relevant to the interpretation of the test results;
x. Name of the person requesting the test to be conducted for the patient

e) [NEW] Safety records

i. Safety measures implemented

Share your feedback with us by 7 May 2021

https://go.gov.sg/hcsa-clinical-lab-feedback

Stay connected with us

MOH will provide more information along the way

*Visit **HCSA.SG** for more information*

Write to us at HCSA_Enquiries@moh.gov.sg

The End

Thank you

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Annex – Draft LTCs

Clinical laboratory reports

- The clinical laboratory report must include the following information:
  - The test results, units of measurement and reference intervals
  - Any interpretative comments
  - Any condition that may affect the validity of the test results

Laboratory safety requirements

- The licensee must **develop and implement policies and processes** for
  - Control of exposure to blood borne pathogens and other hazardous substances including liquid nitrogen and UV light
  - Reception and handling of specimens, and control of any spill of blood and other body fluids
  - Waste management
  - Electrical safety, safety of water supply and outlets, and safety of equipment
  - Handling and disposal of sharp apparatus and objects which can readily puncture or cut human skin when encountered
  - Performance of all tests
  - Functioning and maintenance of equipment
  - Undertaking of all duties by all staff
  - Safety equipment including safety cabinets, hand basins and emergency showers
  - Ventilation, lighting and noise level
  - Security

Facilities and equipment

- The facilities for the storage of blood and blood products, pre-transfusion testing samples are appropriate for the activities undertaken
  - There is a physical segregation of crossmatched and uncrossmatched blood and blood products
  - Pre-transfusion testing samples and reagents are stored separately from blood and blood products

- The equipment used for storage and transport of blood and blood products shall be effective in ensuring that blood and blood products remain safe for transfusion
  - The equipment and conditions for storage of blood and blood products are appropriate for the maintaining the integrity/viability of the blood and blood product
  - There is continuous monitoring of the storage conditions
  - There is an effective mechanism for the prompt investigation and rectification if the storage conditions fall outside of the acceptable limits

Quality control

- There are quality control measures to ensure the validity of the pre-transfusion testing results
  - E.g. the potency and reliability of the following reagents are tested for reactivity on each day of use:
    - Antisera
    - Reagent red cells

Laboratory practices

- There are effective measures to ensure the safety of the patients receiving blood and blood product transfusion
  - There is a process to verify that:
    - Identify discrepancies between patient's identification on the pre-transfusion testing request and sample before pre-transfusion testing is performed
    - The pre-transfusion testing sample is traceable to the person who performed the phlebotomy
  - There is a process to verify the patient's ABO and Rh blood group, and red cell antibody screening results
  - There is forward and reverse blood grouping to determine the patient's blood group
  - Red cell antibodies are screened and identified if present
  - There are measures in place to minimize the risks of transcription errors
  - The ABO and Rh blood group of red cell concentrates are verified prior to their release into the inventory
  - There are measures to prevent mix-up of blood and blood products at the time of release for transfusions
  - There is a process for accepting blood and blood products back into the inventory after they have been issued:
    - The blood and blood product had been maintained at appropriate temperature
    - The blood and blood products have been inspected and deemed acceptable for transfusion
    - At least one sealed segment of integral donor tubing remained attached to the blood pack for compatibility testing, if applicable

Incident management

- There is a written procedure for the escalation and investigation of the suspected transfusion reactions or incidents that are reported to the laboratory to be initiated as soon as possible to facilitate the continuing care of patient

Records

- Transfusion and related records are retained for an appropriate period
  - E.g. blood and blood product storage equipment maintenance and preventive maintenance:
    - Temperature monitoring
    - Alarm testing
    - Validation of insulated boxes
    - Calibration to a reference standard
  - Blood and blood product inventory
  - Quality control and proficiency testing
  - Patients' group and crossmatch results, and transfusion records
  - Disposition of all blood and blood products
  - Investigation of transfusion reaction and transfusion-related laboratory errors