01.	Patient Name	
02.	Father's Name	
03.	Age	
04.	CNIC	
05.	Contact Number	
06.	Referring Physician	
07.	Address	

Referred test: Anti Rubella (IgM) through ELISA

History:

Comments:

SOPs to be followed:

1. Ship specimens for testing as soon as possible.
2. Samples must be collected in gel/serum separator tube (tiger top tube)
3. Clearly label the tube with a permanent marker.
4. Complete the patient investigation form.
5. Pack the tube in proper packaging.
6. Cover spill completely with paper towels and pour disinfectant solution (0.5% sodium hypochlorite) over paper towels. Allow paper towels soaked with disinfectant to stand for 30 minutes. Clean up the spill. Rinse area with 70% ethanol or water. Place spill clean-up materials in a biomedical waste container (yellow bag). Wash hands with soap and water.
7. Include a frozen cold pack with the specimen.
8. Write the address on the packaging.
9. Surgical mask and gloves are recommended for all procedure.

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ELISA Section

Immunology and Serology Lab

PHRL, KMU phase 5, Peshawar. Contact number:

Rubella

Rubella is a virus-borne infectious illness. Rubella causes a mild sickness in most individuals, with symptoms such as a low-grade fever, sore throat, and a rash that begins on the face and spreads to the rest of the body. If a woman is infected with rubella while she is pregnant, it might result in a miscarriage or major birth abnormalities in the kid. MMR (measles-mumps-rubella) vaccination provides the greatest protection against rubella.

Signs and Symptoms

Rubella is typically mild in children, with minimal symptoms. A red rash is usually the first sign in youngsters who do experience symptoms. Other symptoms that may occur 1 to 5 days before the rash appears include:

- a low-grade fever
- headache
- mild pink eye (redness or swelling of the white of the eye)
- general discomfort
- swollen and enlarged lymph nodes
- cough
- runny nose

Rubella causes a moderate sickness in most people, with a low-grade fever, sore throat, and a rash that begins on the face and spreads to the rest of the body.

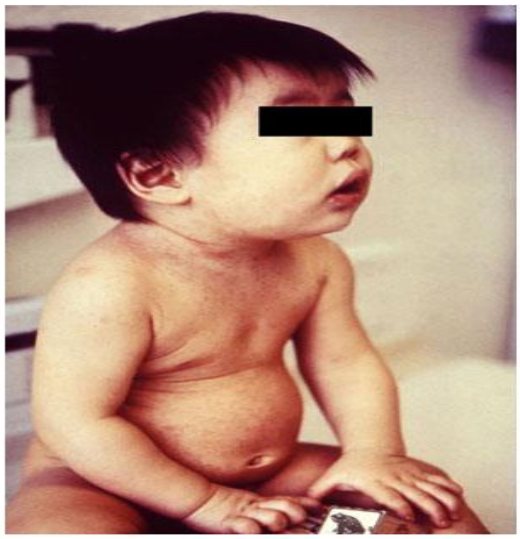
Before the rash forms, some individuals may have headaches, pink eye, and overall discomfort.

About 25 to 50 percent of rubella infected persons will not show any symptoms.

Transmission

Rubella spreads when an infected person coughs or sneezes. Also, if a woman is infected with rubella while she is pregnant, she can pass it to her developing baby and cause serious harm.

A person with rubella may spread the disease to others up to one week before the rash appears, and remain contagious up to 7 days after. However, 25% to 50% of people infected with rubella do not develop a rash or have any symptoms, but they still spread it to others.



This is baby has a mild rash with pink and red spots caused by rubella

Serological Testing

Serologic Testing for Rubella and CRS (congenital rubella syndrome) in Low Prevalence Setting.

IgM and IgG Detection

Detection of specific IgM antibodies in a serum sample collected within the first few days after rash onset can provide presumptive evidence of a current or recent rubella virus infection. The optimum time-point for collection of serum is five days after the onset of symptoms (fever and rash) when >90% of cases will be IgM positive.

On the day of rash onset only about 50% of cases are IgM positive. Therefore, if serum collected less than five days after onset is negative, a second sample would be necessary to confirm/rule out rubella.

Serological testing for congenital rubella syndrome (CRS)

Congenital Rubella Syndrome (CRS), which can occur when a woman is infected with rubella during a pregnancy, consists of a variety of possible birth defects including cataracts, hearing loss, heart defects, developmental disabilities, and low birthweight. CRS cases can be diagnosed in newborns and young infants using detection of rubella IgM. Suspected cases should be tested as close to birth as possible and again at 1 month of age if the initial IgM test is negative. If paired sera are to be collected, the second sample should be collected 14 to 21 days after the acute specimen was collected. At 3 months of age, approximately 50% of cases would still have detectable rubella IgM in their serum. Additionally, the presence of rubella IgG in an infant after the decline of maternal antibodies (9 months of age) and the absence of vaccination or exposure to rubella will confirm CRS.

1.0 Purpose

To maintain patient safety by providing consistent method for correct identification, sample collection, transportation, receiving and/or rejection of specimens of suspected patients for Rubella.

2.0 Scope

This policy applies to all staff and areas of Clinical Laboratory where samples are collected, received, registered, processed, archive and disposal by maintaining standards.

3.0 Responsibility

3.1 All staff receiving samples must comply with the procedure in acceptance and rejection of samples.

3.2 Lab Head and Managers/Assistant Managers/Coordinator are responsible for implementation and monitoring of policies/procedures.

3.3 Managers/Assistant Managers/Coordinators are also responsible for providing awareness and understanding of policy.

3.4 Senior Coordinator, QA is responsible for revision and updating of policy.

3.5 Laboratory Director and Senior Administrator are responsible for the approval.

4.0 Procedure

4.1 Proper Personal Protective Equipment should be used while handling biological specimen.

4.2 Specimens are transported to receiving area in individual plastic bags (zip lock bags) in a labeled transportation box accompanied by requisition slip.

4.3 Upon arrival following steps must be taken:

4.3.1 Remove the sample from the rack or bag as per required safety precautions.

4.3.2 Check that the specimen tube/container is firmly capped and with no leakage.

4.3.3 Store samples at room temperature for up to 24 hours.

4.3.4 If you need to store the sample for one week before shipping, store between 0-5° Celsius.

4.3.5 Avoid freezing whole blood samples.

4.3.6 Read the patient's full name and L# from the requisition slip.

4.3.7 Check the sample is labeled with same name and identification number.

4.3.8 If the sample is unlabeled or poorly labeled treat it as rejected sample (see rejection criteria Policy Document No. KMU/PHRL/SOP-04)

4.3.9 All patient information provided on requisition slip should be clear, unambiguous and allow for unequivocal identification of the patient, the requesting physician, patient location, clinical details and investigations where required.

4.4 Technologist must read the requisition slip for any additional comments/remarks for example STAT test (STAT laboratory tests and services are those that are needed immediately to manage medical emergencies) and request for special processing.

4.5 Samples received from outreach collection units at outreach Lab are check for the patient's full name and MR# or Lab# from the requisition slip and check the sample is labeled with same name and identification number then distributed to respective sub-section/ benches.

4.6 Specimens are then sorted according to laboratory sub-section on priority basis. If test request received marked with "STAT" sample must be delivered to sub-section immediately with special attention and test should be carried out within specified time of STAT tests.

4.7 If necessary samples are spun and aliquot prepared.

4.8 Depending upon the tests requested, all samples are may be stored at room temperature (15°-30°C) for up to two hours prior to testing or transferred immediately to clod chain storage of other diseases testing lab

4.9 If the sample is satisfactory and need to be shared with any other sub section/benches of clinical laboratory, make aliquots with proper identification and it should be sent immediately to relevant sub section/benches along with requisition slip.

4.10 If sample is accepted in the outreach laboratory or Collection center, it is the responsibility of outreach laboratory staff to protect the sample according to the outreach laboratory retention policy.

4.11 Receiving bench technologists are responsible for taking out list of samples from LIMS/IPMS that is collected and not received in laboratory; after defined period of time it should be informed to relevant area supervisor (Reception or Laboratory

Outreach Support Centre) immediately for retrieval of specimen to avoid delay in processing and reporting.

4.12 All unsatisfactory samples entered in the computer record are immediately cancelled stating the reason for rejection. All such information is documented in the comments section of the LIMS (Laboratory Information Management System).

4.13 Unsatisfactory sample will not be returned back to in-patient area and is stored according to the sample retention policy of Outreach Lab.

5.0 General Notes for Handling Reagents and/or Samples

5.1 Handle all specimens as if they contain infectious agents

5.2 Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

5.3 The work area/benches are disinfected before and after the test(s) performed to avoid any bio-hazards risk.

5.4 During processing samples, staff must wear proper PPE (Personal protective equipment).

5.5 Mouth pipetting of any chemical or sample material is completely prohibited.

5.6 Precaution should be taken to avoid punctures, cuts and any open skin wounds.

5.7 Adhere and follow safety guidelines when handling chemicals and infectious sample materials.

5.8 Contain waste appropriately for disposal.

5.9 Gloves should be removed in such a way that the skin does not come into contact with the external surface of the glove.

5.10 Do not handle taps, phone, switches and door handle directly, while working with infectious sample.

5.11 Wash hand thoroughly after processing samples.

6.0 REFERENCE

7.0 APPROVAL

Prepared by	
Name & Designation	Signature & Date
Reviewed by	
Name & Designation	Signature & Date
Name & Designation	Signature & Date
Approved by	
Name & Designation	Signature & Date

Public Health Reference Laboratory (PHRL) is committed to provide quality services for disease surveillance through Integrated Disease Surveillance and Response (IDSR) in Khyber Pakhtunkhwa province.

8.0 Purpose

To describe the laboratory procedures for Rubella Sample Packing and Transportation to PHRL, KMU.

9.0 Scope

These Standard Operating Procedures provide a template agreed by PHRLs that is essential for guiding responses to infectious disease outbreaks by public health practitioners, epidemiologists and clinicians.

10.0 Responsibility

10.1 Doing: Lab in charge/Team lead/Technicians.

10.2 Checking/Reporting: Consultants/Reporting group.

10.3 All trained personnel are responsible to handle and test samples suspected of containing Hepatitis B.

10.4 Laboratory Director/Senior Administrator are responsible for the approval, implementation, validation, maintenance and review of this procedure.

11.0 Procedure

11.1 Specimen Packing and Transportation

11.1.1 Samples container (blood/sera tubes) must be properly labelled with double identification marks i.e. NAME & Sample ID perfectly reflecting the excel sheet attached.

11.1.2 Absorbent materials should be in sufficient quantity to absorb the entire liquid content if the primary container (s) leak.

11.1.3 Leak proof secondary container, cushioning material e.g. bubble wrap, tape to seal the outer package (if required).

11.1.4 Excel sheets of the samples must be double checked for any duplication, in case of similarity in names.

11.1.5 Laboratory form or letter describing the main epidemiological and clinical findings and the lab tests that are required

11.1.6 Make sure that samples must be sorted in small groups of 05-10/ bag, with individual requisition/Referral form for all samples attached/inserted in the pocket.

11.1.7 After collection and packaging the sample, it must be immediately sent to PHRL-KMU.

11.1.8 Receiver name, address and telephone number.

11.2 Specimen Rejection Criteria

11.2.1 If specimen does not meet acceptable criteria it may be rejected by the laboratory. The following are criteria used for the possible rejection of specimens:

11.2.2 Specimen improperly labeled as to the patient identity (as per above criteria)

11.2.3 Patient identification mismatched between specimen and requisition form/ excel sheet data.

11.2.4 Improper collection container i.e., leakage or broken sample tube or container.

11.2.5 Sample collection date is older than 7 days from the date of receiving.

11.2.6 Improperly transported (i.e., not on required temperature)

11.2.7 Specimen contaminated with biological hazardous material.

General Notes

- All Labs can coordinate and follow-up the results on 091-9219651 and each Lab are expected to maintain complete record of samples sending, results and communication with PHRL focal person.

- For any further assistance Mr. Abdul Qadoos khan (Lab Technologist) may be contacted through email:aqkhan.kmu@gmail.com