Technical Specifications for Dengue NS1 antigen ELISA Kit

1. The ELISA kit should be designed for qualitative detection of dengue NS1 antigen of all 4 dengue serotypes in human serum.
2. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
3. The kit should have approval of the statutory authority from the country of origin
4. In case of imported kits it should be registered and licensed by the DCG(I)
5. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India
6. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port of discharge of consignees.
7. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs .
8. The assay components should be sufficient for the 96 tests provided in four runs.
9. The ELISA kit for detection of dengue NS1 antigen should have a sensitivity of ≥90% and a specificity of ≥95% taking RT-PCR as the gold standard.
10. The kit should be provided with the following materials and reagents:
    a) Anti- NS1 Antibody Coated BreakwayMicrowells (12*8=96 wells). Desiccant should be provided for storing the unused microwells which are to be resealed immediately.
    b) Horseradish peroxidase conjugated Anti-NS1 monoclonal antibody with preservatives
    c) Chromogenic substrate in buffer.
    d) Positive Control, Negative control &Calibrators in the form of recombinant antigen.
    e) Sample diluents&Wash buffer

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.

Technical Specifications for DengueIgMELISA Kit

1. Assay should be based on the principle of "IgMCapture ELISA "
2. The assay should detect IgM antibodies against all 4Dengue virusserotypesin serum.
3. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin
5. In case of imported kits it should be registered and licensed by the DCG(I)
6. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India
7. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port of discharge of consignees.
8. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs .
9. The assay components should be sufficient for the 96 tests provided in four runs.
10. The assay should have sensitivity ≥ 94% and specificity of ≥98%.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.

Technical Specifications for ChikungunyaIgM ELISA Kit

1. Assay should be based on the principle of "IgM capture Elisa"
2. The assay should detect IgMantibodies against Chikungunya virus in serum.
3. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin
5. In case of imported kits it should be registered and licensed by the DCG(I)
6. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India
7. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port of discharge of consignees.
8. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs .
9. The assay components should be sufficient for the 96 tests provided.
10. The assay should have sensitivity $\geq$ 95% and specificity of $\geq$ 98%.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.

Technical Specifications for LeptospiraIgMELISA Kit

1. Assay should be based on the principle of "IgMELISA "
2. The assay should detect IgMantibodies against Leptospira in serum.
3. Adequate documents detailing the principle, components,biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin
5. In case of imported kits it should be registered and licensed by the DCG(I)
6. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India
7. The kit should have minimum shelf life of 60% or 12 months(whichever is more) at the port of discharge of consignees.
8. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs .
9. The assay components should be sufficient for the 96 tests provided in four runs.
10. The assay should have sensitivity of ≥96% and specificity of ≥ 98%.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.

Technical Specifications for Japanese EncephalitisIgMELISA Kit

1. Assay should be based on the principle of "IgMCaptureElisa"
2. The assay should detect IgMantibodiesto JE virus in serum and CSF.
3. Adequate documents detailing the principle, components, biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin
5. In case of imported kits it should be registered and licensed by the DCG(I)
6. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India
7. The kit should have minimum shelf life of 60% or 12 months(whichever is more) at the port of discharge of consignees.
8. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs .
9. The assay components should be sufficient for the 96 tests provided in four runs.
10. The assay should have sensitivity of ≥**85%** and specificity of ≥ **90%**.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.

Technical Specifications for Viral Hepatitis A IgM ELISA Kit

1. Assay should be based on the principle of "IgM capture"
2. The assay should detect IgM anti HAV antibodies.
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle ,components ,biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India.
8. The kit should have minimum shelf life of 60% or 12 months (whichever is more) at the port of discharge of consignees.
9. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs.
10. The assay components should be sufficient for the 96 tests provided.
11. The assay should have sensitivity of $\geq$ 99% and specificity of $\geq$ 98%.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.
3. Preferably, 2 kits should be supplied along with the procurement lot of which one kit will be used for validation, subject to which the kits of the same batch and lot no. will be supplied to consignees and one kit will be retained for post market evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters

15/4/2019

Technical Specifications for Viral Hepatitis E IgM ELISA Kit

1. Assay should be based on the principle of "IgM capture"
2. The assay should detect IgM anti HEV antibodies.
3. Should be compatible with plasma and serum both.
4. Adequate documents detailing the principle ,components ,biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
5. The kit should have approval of the statutory authority from the country of origin
6. In case of imported kits it should be registered and licensed by the DCG(I)
7. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India
8. The kit should have minimum shelf life of 60% or 12 months(whichever is more) at the port of discharge of consignees.
9. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs .
10. The assay components should be sufficient for the 96 tests provided in four runs.
11. The assay should have sensitivity of $\geq$ 99% and specificity of $\geq$ 98%.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.
3. Preferably, 2 kits should be supplied along with the procurement lot of which one kit will be used for validation, subject to which the kits of the same batch and lot no. will be supplied to consignees and one kit will be retained for post market evaluation close to the expiry of the kit or in case of legal dispute with regards to performance of the kit as per specified parameters

Technical Specifications for Scrub Typhus IgM ELISA Kit

1. Assay should be qualitative ELISA for the detection of IgM antibodies.
2. The assay should detectIgMAntibodies to *O. tsutsugamushi* (OT) in serum
3. Adequate documents detailing the principle ,components ,biosafety, methodologies, validity criteria, interpretation of results, performance characteristics, storage conditions, limitation of assays, manufacturing and expiry dates should be provided with each kit.
4. The kit should have approval of the statutory authority from the country of origin
5. In case of imported kits it should be registered and licensed by the DCG(I)
6. In case of indigenous manufactures should be licensed by the competent authority defined under Drugs and Cosmetics Act at 1940 and also be evaluated by the centers approved by the Government of India
7. The kit should have minimum shelf life of 60% or 12 months(whichever is more) at the port of discharge of consignees.
8. The assay component should include reactive and non-reactive controls sufficient for at least 4 runs .
9. The assay components should be sufficient for the 96 tests provided in four runs.
10. The assay should have sensitivity and specificity of $\geq$ 90%.

General Specifications

1. The manufacturer/authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C.
2. The kit size should be 96 tests/kit (in strips of 12x8 wells) such that individual strips can be used for testing and the same are compatible with automated ELISA reader and washer.

15/4/2019

Technical Specifications for Bivalent Rapid Diagnostic Test kits for *detecting P.falciparum and P. vivax Malaria* antigen

a) Description of the Test Kit

The Bivalent Rapid Diagnostic Test Kit (RDK) for Malaria should comprise of testcard / strips / cassettes and reagents including buffer solution in a dropping bottle.The test kit should be able to conduct the rapid diagnosis for both *P. falciparum*and *P. vivax.* The test should be based on the principle of capture of parasiteantigen from blood using monoclonal antibodies specific for antigen targets. Eachtest kit should contain all the material required for conducting the test includingindividually packed sterile lancets for pricking, heparinized capillary tubes(diameter -1 mm) with relevant markings and reaction tubes with stand / wells asrequired. The required packing standards and labeling should meet the GoodManufacturing Practices (GMP) standards. The manufacturer should haveInternational Organization for Standardization [ISO] certification. One should beable to perform the test with the blood taken by finger prick of the patient.

There should be evidence of sound product performance in the field. The sampleproducts should be available for pre-purchase assessment. Technical supportshould be available for the product. Terms of replacement for products which failinitial QA tests should also be clearly mentioned. Long-term viability of themanufacturer and adequate manufacturing capacity (to ensure continuous supply)should be there.

Temperature stability data: information on Real-time stability for the lab productand accelerated stability for the purchased lot should be available.

Each batch ofRDK should be tested during time of delivery to ensure sensitivity and specificity as follows:

A. For*P. falciparum* Malaria:Sensitivity and Specificity should be minimum 95% at parasite density level of200 asexual parasites/ul of blood.

B. For*P. vivax* Malaria:

□□Sensitivity: ≥75% at density of 200 parasites/ul

15/4/2019

□□Specificity : ≥ 90%

Type of RDT- Only Histidine-Rich Protein 2 (HRP2) and Parasite lactate dehydrogenase (pLDH) based RDTs to be used and **not aldolase basedones**.

(b) Content of Kit:

Each kit should be hermetically sealed and non-permeable pouch and should havemoisture absorbent material. 10 such test cards / strips should be packed in a boxcontaining the reagents and the test plates. Adequate literature detailing thecomponents, methodologies, validity criteria. Storage conditions, expiry dates andlimitations of test should be provided.

(c) Shelf Life:

Shelf life from manufacturing day to expiry date should be at least 2 years and itshould not pass more than 1/6th of their effective life from the date at the time, thematerial is offered for inspection.

Losses due to premature deterioration as a result of biological and other activitiesduring the life of potency of the Rapid Diagnostic Test kits will be made good bythe firm at their cost.

(d) Marking /Labeling:

(i) Each card /strip / cassettes should have space for patients particulars anddate of the test

(ii) The box should have the following markings

a. Name of the test

b. Lot number

c. Manufacturing and expiry date

d. Name of the manufacturer with address

e. Details of the content

f. Storage conditions

g. Handling procedures

h. Disposal instruction for the box and its contents

(e) Details regarding approval of license

(i) Manufacturing and Marketing License for manufacturing of Rapid MalariaDiagnostic Kits should have been obtained from the concerned Regulatoryauthority in the country by the manufacturer at the time of tender opening.

(ii) The Bidders must submit scientific study report in support of their claim ofsensitivity and specificity of the offered product from an institution recognizedfor the purpose. RDK should be stable up to 40°C claim should be supportedby actual shelf life studies.

(iii) The Bidders must submit a sample of their product for technical evaluation.

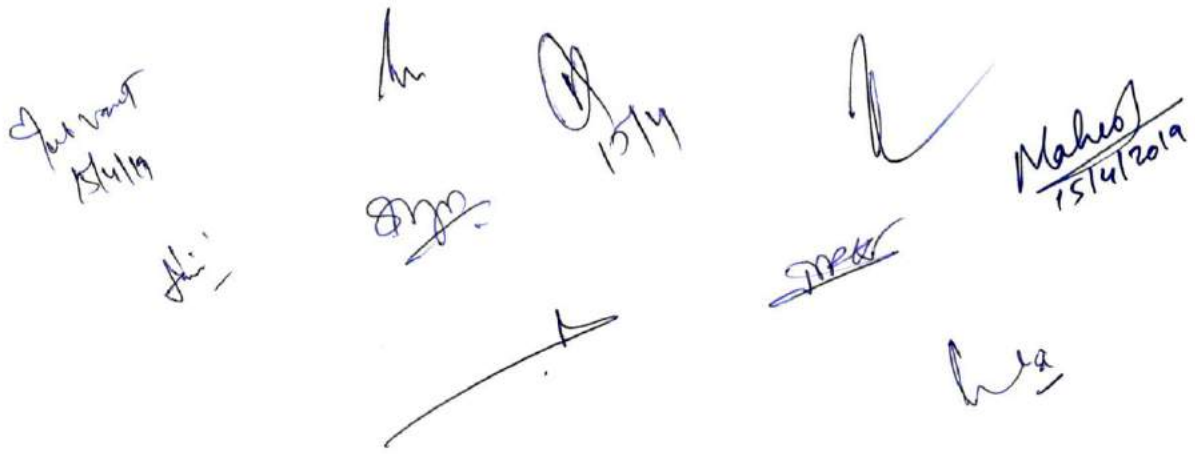
(iv) Recommended condition for storage (e.g. room temperature) and shelf lifeshould clearly be mentioned on the label of RDK.

Technical Specifications for Widal test kit (Slide/Tube)

1. Kit should have Stained salmonella antigens for "O", "H," Para-A, Para-B,
2. Shelf life period should be minimum 1 year to the end user from the date of supply.
3. The kit should be supplied complete with necessary accessories required for the test.
4. Sufficient controls must be provided with test kit.
5. Kit should be ISO 13485 / DCG(I) approved
6. Detailed literature regarding Kit should be provided along with tender.

General Specification:

Kit should be stored & transported at 2*C to 8*C temperature.



The following experts participated in the 1st Meeting of "Laboratory Strengthening" Committee of IDSP, Held at Central Seminar Room on 15-04-19.

Agenda of meeting: Finalization of Technical specification for Diagnostic Kits for IDSP

S.No	Name	Institute/Designation	Signature
1.	Dr. Mala Chabbra	Senior Consultant, RML Hospital Delhi. Chair person	
2.	Dr. Pradeep Khasnobis	Joint Director, NCDC, Delhi	
3.	Dr. V.S Randhank	Director Professor, Dept of Microbiology, LHMC, Delhi	
4.	Dr. V.S Dhruwey	Lab Coordinator, State of Gujarat.	
5.	Dr. S Raju	Deputy Director(State Public Health Laboratories) & State Lab.Coordinator(IDSP)	
6.	Dr. Manisha Jain	Associate Professor, VMMC & SJH, Delhi	
7.	Dr. Mala Vinayak	Specialist Gr- I (Microbiology) GNCT Delhi	
8.	Ms. Monika Vashisht	State Microbiologist, Punjab	
9.	Ms. Prameela	State Microbiologist, Karnataka	
10.	Dr. Mahesh Waghmare	Assistant Director, NCDC, Delhi Member Secretary.	