Anti-HCV Antibody Kits (Rapid Test)- whole blood

1. Should utilize recombinant and /or synthetic peptide antigens for core, NS3, NS4 and NS5.
2. The assay should detect total anti HCV antibodies.
3. Should be compatible with whole blood.
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 in 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. Indigenous manufactures should be licensed by the competent authority/Licensing authority defined under Drugs and Cosmetics Act (1940) and medical device rule 2017.
8. The kit should have minimum residual shelf life of 60% or 12 months (whichever is more) at the port/place of discharge of consignees.
9. The total procedure time shall not be more than 30 minutes.
10. The assay component should include positive and negative controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls) which may be provided along with the kits if not a part of the kit.
11. The assay should have sensitivity more than or equal to 99%and specificity of more than or equal to 98% as per the office order of MoHFW vide F. No. 29/Misc./4/2016-DC(65) dated 12/07/2017.
12. The control dot/band should be visible to the naked eye and be able to detect the presence of human immunoglobulin and should not be just a "procedural control" or meant merely for checking the flow of reagents or integrity of antigens except in lateral flow technology.

General Specifications

1. The manufacturer /authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2-8^0 C. The cumulative time temperature indicator technology should be used on each kit and be pre-qualified by WHO.
2. The pack size of kit should not be more than 50 tests wherein each test is individually packed.
3. 8 kits should be supplied along with the procurement lot of which four kits will be used for validation, subject to which the kits of each batch and lot no. will be

supplied to program and four kits will be retained for 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.

4. The kit will be evaluated on the above parameters by the centers approved by the program.

The committee approved the specification of Anti HCV antibody (rapid test) on whole blood samples

4/10/22

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