MINUTES OF MEETING OF GRIEVANCE REDRESSAL COMMITTEE AGAINST TECHNICAL EVALUATION REPORT FOR THE PROCUREMENT OF RAPID DIANOSTIC KITS OTHER TESTING STRIPS THROUGH OPEN COMEPTITIVE BIDDING FOR FINANCIAL YEAR 2023-24

Sr. No	Name of Firm	Item name	Reason for Rejection	Grievance of Firm	Decision of the Committee
1	Sind Medical Stores			Dear Sir, M/S Zedco has quoted; Bioline Anti HCV Rapid ICT Test 02FK10 Abbott, Korea manufacturer: Abbott Diagnostic Korea Inc (Formerly Known as Standard Diagnostic, Inc Recombinant HCV core, NS3, NS4, NS5 used as capture materials. The NS2 Ag is missing in this product therefore this product is incomplete and not suitable for screening due to incomplete antigen glycoprotein panel. NS2 is found in the Pakistani population and it plays a major role in HCV infection. Further, the required synthetic corresponding glycoprotein/ recombinant HCV antigen Core, NS2, NS3, NS4, NS5 is available in the product quoted by our firm. Health department government of Punjab is working actively in eliminating hepatitis C viruses; therefore, keeping in view this agenda, a complete product with the maximum range of glycoprotein must be selected for procurement. As the specificationfor Anti-HCV was not specified for which we have also notified before the tender opening. Keeping in view the facts, M/S Zedco's quoted product Bioline Anti-HCV must not be entertained for procurement.	Mr. Amjad from Sind Medical Stores Pvt Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Evaluation Criteria and announced Technical Evaluation Report. The committee after due deliberation and discussion unanimously decided that: 1. NS2 is a viral protein found in Hepatitis C virus and also produced by influenza virus, and is alternatively known as Nuclear Export Protein (NEP). All the major products including CLIA and ELISA (confirmatory tests) detects HCV Core protein, NS3, NS4, NS5. During the lab testing the results of the said quoted product was up to mark and declared satisfactory by end user. Though there is no concrete evidence regarding M/s Sind Medical Store claim of high prevalence of NS2 in Pakistani population and its role in HCV spread. Hence, based on the technical input of end user the grievance is rejected unanimously and the decision of the technical committee was upheld and the status of the quoted item will remain **Responsive.**
2	Lab Diagnostic systems (SMC) Pvt Ltd.	HEPATITIS B SURFACE ANTIGEN (HBsAg) RAPID DIAGNOSTIC TESTING KITS / DEVICES	1. Valid GMP certificate not attached. 2. The offered specifications of the qouted item not complied 100% with the advertised technical specifiations. 3. Quality certification of the quoted product not attached. 4. The delivery challan and satisfactory report of the submitted PO not attached. 5. Undertaking regarding the acceptance of all the terms and conditions by the applicant as mentioned in bidding documents not attached. 6. The shelf life on certificate of analysis of the quoted product not as mentioned on enlistment certificate.	Respected Sir, Clarifications are as under for kind consideration of grievance committee. **Hepatitis B surface Antigen RDT kits/devices**: 1. Valid GMP certificate attached with this letter 2. The offered specification has listed international certificates such as WHO PQ/US FDA. LDS Pakistan is the first Pioneer IVD local manufacturer, licensed by DRAP having Mfg License # ELM-0028, fully complaint and certified ISO 13485 & GMP. So as a local IVD manufacturer, LDS fulfills regulations and certification for sale in Pakistan. 3. Quality certificates i.e., DRAP registration certificate and ISO 13485 attached with this letter. 4. Delivery Challan and satisfactory report of the POs are attached 5. Undertaking regarding the acceptance of all the terms and conditions, attached. 6. R-test HBsAg Rapid Test has approved shelf life of 24 months. Attached DRAP approval letter.	Mr. M. Shahid Iqbal from Lab Diagnostic systems (SMC) Pvt Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Evaluation Criteria and announced the Technical Evaluation Report. The committee after due deliberation and discussion decided that: 1. The firm did not provide valid GMP certificate issued by DRAP; hence, the grievance of the firm was not accepted to the extent of this parameter. 2. The quoted item does not comply 100% with the advertised technical specifiations; hence, the grievance of the firm was not accepted to the extent of this parameter. 3. The firm did not provide quality certification of the quoted product as specified in Annexure-K of the advertised bidding document. 4. The firm did not provide delivery challan and satisfactory report of the submitted PO; hence, the grievance of the firm was not accepted to the extent of this parameter. 5. The firm did not provide undertaking regarding the acceptance of all the terms and conditions by the applicant as mentioned in bidding documents; hence, the grievance of the firm was not accepted to the extent of this parameter. 6. The firm did not provide certificate of analysis of the quoted product with the shelf life as mentioned on enlistment certificate; hence, the grievance of the firm was not accepted to the extent of this parameter. Hence, the status of the quoted item remained **Non-Responsive.**
3	Lab Diagnostic systems (SMC) Pvt Ltd.	HEPATITIS C (Anti-HCV) RAPID DIAGNOSTIC TESTING KITS/DEVICES	1. Valid GMP certificate not attached. 2. The offered specifications of the qouted item not complied 100% with the advertised technical specifiations. 3. Quality certification of the quoted product not attached. 4. One year experience of the quoted product in Public sector since 2019 not attached. 5. Undertaking regarding the acceptance of all the terms and conditions by the applicant as mentioned in bidding documents not attached.	**HEPATITIS C (Anti-HCV) RDTs/Devices:** 1. Valid GMP certificate attached at Annexure 1. Again, attached with this letter. 2. The offered specification has listed international certificates such as WHO PQ/US FDA. LDS Pakistan is the first Pioneer IVD local manufacturer, licensed by DRAP having Mfg License # ELM-0028, fully complaint and certified ISO 13485 & GMP. So as a local IVD manufacturer, LDS fulfills regulations and certification for sale in Pakistan. 3. Quality certificates i.e., DRAP registration certificate and ISO 13485 have been enclosed at Annexure 2. Again, attached with this letter. registration certificate and ISO 13485 have been enclosed at Annexure 2. Again, attached with this letter. 4. DCs and satisfactory report of POs are attached. 5. Undertaking regarding the acceptance of all the terms and conditions is enclosed in the bid at pg. no. 183. Again, attaching here for reference.	1. The firm did not provide valid GMP certificate issued by DRAP; hence, the grievance of the firm was not accepted to the extent of this parameter. 2. The quoted item does not comply 100% with the advertised technical specifiations; hence, the grievance of the firm was not accepted to the extent of this parameter. 3. The firm did not provide quality certification of the quoted product as specified in Annexure-K of the advertised bidding document. 4. The firm did not provide one year experience of the quoted product in public sector since 2019; hence, the grievance of the firm was not accepted to the extent of this parameter. 5. The firm did not provide undertaking regarding the acceptance of all the terms and conditions by the applicant as mentioned in bidding documents; hence, the grievance of the firm was not accepted to the extent of this parameter. Hence, the status of the quoted item remained **Non-Responsive.**
4	Lab Diagnostic systems (SMC) Pvt Ltd.	PREGNANCY TEST STRIPS	1. Valid GMP certificate not attached. 2. The offered specifications of the qouted item not complied 100% with the advertised technical specifiations. 3. Quality certification of the quoted product not attached. 4. One year experience of the quoted product in Public sector since 2019 not attached. 5. Undertaking regarding the acceptance of all the terms and conditions by the applicant as mentioned in bidding documents not attached.	**PREGNANCY TEST STRIPS:** 1. Valid GMP certificate attached at Annexure 1. Again, attached with this letter. 2. The offered specification has listed international certificates such as WHO PQ/US FDA. LDS Pakistan is the first Pioneer IVD local manufacturer, licensed by DRAP having Mfg License # ELM-0028, fully complaint and certified ISO 13485 & GMP. So as a local IVD manufacturer, LDS fulfills regulations and certification for sale in Pakistan. 3. Quality certificates i.e., DRAP registration certificate and ISO 13485 have been enclosed at Annexure 2. Again, attached with this letter. registration certificate and ISO 13485 have been enclosed at Annexure 2. Again, attached with this letter. 4. DCs and satisfactory report of POs are attached. 5. Undertaking regarding the acceptance of all the terms and conditions is enclosed in the bid at pg. no. 183. Again, attaching here for reference. We would also like to take this opportunity to record our protest against the specifications thatappear to favor imported products over locally manufactured ones. We believe that the tender authority has shown a lack of consideration for local manufacturers by making international certifications such as US FDA and WHO Pre-Qualification compulsory criteria for bid qualification in the case of Rapid Diagnostic Tests. We strongly argue that the inland rules & regulations (DRAP registration) should be the primary criterion for evaluating the quality of locally manufactured products. Lab Diagnostic Systems (SMC) Pvt Ltd, has invested significant resources and effort to comply with the stringent regulations and standards set by DRAP. All our products are DRAP registered, have undergone successful evaluations and are being used by esteemed public and private institutions such as AFIP, all CMHS, IBTS, NIH, Children Hospital Multan, Lahore General Hospital, HMC, Sheikh Zayd Hospital RYK & others. Furthermore, it is essential to highlight that for locally manufactured drugs which are to be used in-vivo, registration by DRAP is already considered the highest quality criterion. DRAP registration is always accepted in all tenders and international quality conformance such as USFDA or MHRA approval is not required. And no one in the local industry, out of 750 pharmaceutical companies, has such stringent regulation adopted and yet it is the biggest industry. In contrast, when it comes to In-Vitro Diagnostic (IVD) products, which are essentially screening tests and do not carry the same critical importance as drugs intended for in-vivo use, they are subjected to criteria such as WHO Pre-Qualification or US FDA approval, which are among the most stringent in the world. This raises a pertinent question: Does the tender authority expect our emerging local IVD industry, with only one manufacturer, to undertake the substantial financial logistical burdens of meeting the requirements of WHO PQ and US FDA merely to qualify for local tenders? The cost implications of these certifications need to be considered, as they are substantial. We also extend an invitation to the tender authority to consider running a parallel trial involving 1000 to 5000, or any other suitable number of tests, to demonstrate that locally manufactured products, based on local strains, can produce results comparable to international standards. This approach not only provides an opportunity to assess the quality and reliability of locally made products but also presents an avenue for significant cost savings. By opening the bid to both local and international participants, you can make an informed comparison and evaluate the potential benefits of supporting domestic production. We kindly urge the committee to give due consideration to local manufacturers and not evaluate both imported and local products against the same criteria. By favouring local manufacturers, not only can we promote domestic industries, but it can also lead to significant cost savings. Thank you.	1. The firm did not provide valid GMP certificate issued by DRAP; hence, the grievance of the firm was not accepted to the extent of this parameter. 2. The quoted item does not comply 100% with the advertised technical specifiations; hence, the grievance of the firm was not accepted to the extent of this parameter. 3. The firm did not provide quality certification of the quoted product as specified in Annexure-K of the advertised bidding document. 4. The firm did not provide one year experience of the quoted product in public sector since 2019; hence, the grievance of the firm was not accepted to the extent of this parameter. 5. The firm did not provide undertaking regarding the acceptance of all the terms and conditions by the applicant as mentioned in bidding documents; hence, the grievance of the firm was not accepted to the extent of this parameter. Hence, the status of the quoted item remained **Non-Responsive.** As the advertised specifications are received by the respective program; hence, DGHS being the procuring agenecy cannot ammend the specifications/requirements.
5	Lab Diagnostic systems (SMC) Pvt Ltd.	CHOLERA Ag 01/0139 (RDTs)	1. Valid GMP certificate not attached. 2. The offered specifications of the qouted item not complied 100% with the advertised technical specifiations. 3. Quality certification of the quoted product not attached. 4. One year experience of the quoted product in Public sector since 2019 not attached. 5. Undertaking regarding the acceptance of all the terms and conditions by the applicant as mentioned in bidding documents not attached. 6. Certificate of analysis of the quoted product not attached. 7. The samples not submitted.		The firm did not contest for the quoted item.

MINUTES OF MEETING OF GRIEVANCE REDRESSAL COMMITTEE AGAINST TECHNICAL EVALUATION REPORT FOR THE PROCUREMENT OF RAPID DIANOSTIC KITS OTHER TESTING STRIPS THROUGH OPEN COMEPTITIVE BIDDING FOR FINANCIAL YEAR 2023-24

6	Popular International Pvt Ltd.	PREGNANCY TEST STRIPS	1. Establishment registration certificate not attached. 2. Valid drug sale license not attached. 3. Specfications of quoted item not offered on bid cover sheet. 4. One year experience of the quoted product in Public sector since 2019 not attached. 5. Manufacturer certificate of analysis not attached. 6. The samples not submitted.	Dear Sir, With reference to your uploaded technical evaluation report for the procurement of rapid diagnostic kits & other testing strips for the financial year 2023-24 on website of DGHS on dated 06-10-203 where we have found our bid has not beenconsidered on the basis of the following documents not attached with our submitted bid. 1. Establishment registration certificate not (Application copy attached). 2. Valid Drug Sales License not attached (Applied for the renewal in DRAP, copy attached). 3. Specifications of quoted item not offered on bid cover sheet (attached). 4. One year experience of the quoted product in public sector since 2019 not attached (Purchase orders attached of the quoted item). 5. Manufacturer certificate of Analysis not attached (Copy attached). 6. Sample not submitted (Ready to re-submit). Regarding submission of samples against quoted item which is WHO recommended and FDA approved we tried to submit of samples but not accepted by the committee as we were late for 10-15 minutes. We are still ready to provide the samples if the committee accept our grievance. Looking forward for your kind consideration.	No represenative from Popular International Pvt Ltd. attended the meeting. The committee examined the documents submitted by the firm along with its grievance application in light of the advertised Evaluation Criteria and announced the Technical Evaluation Report. The committee after due deliberation and discussion decided that: 1. The firm provided renewel application of establishment registration certificate, which was accepted. 2. The firm provided renewel application of drug sale license, which was accepted. 3. The firm mentioned specifications of quoted item that comply with the advertised specifications, which was accepted. 4. The firm provided documents of one year experience of the quoted product in public sector institution, which were accepted. 5. The firm provided manufacturer certificate of ananlysis showing shelf life which is in accordance with the enlistment certificate, which was acceped. 6. As per advertised bidding document, the bidder is required to submit two packs/samples of the quoted brand of each quoted item along with its bid for evaluation by end user so, samples can not be accepted at this stage; hence, the grievance of the firm was not accepted to the extent of this parameter. Hence, the status of the quoted item remained **Non-Responsive.**