

**MINUTES OF THE TECHNICAL COMMITTEE MEETING HELD ON DT. 14/08/2024 AT 12.00 PM REGARDING FURTHER AMENDMENT/CORRIGENDUM ON TECHNICAL SPECIFICATION BASED ON QUERIES REQUESTED BY PROSPECTIVE BIDDERS AGAINST THE AMENDMENT PUBLISHED VIDE NOTIFICATION NUMBER 5030 DTD 22/07/2024 and Bid Reference No. OSMCL/2023-24/EQP-HLAB/31,  
Tender for Supply, Installation & Commissioning of Equipment for setting up of HLA Laboratory at Dept. of Transfusion medicine of SCBMC&HCuttack.**

Notification No. **6016**

Date: **27.08.2024**

**Item Sl.no-1: Fluoro Analyzer HLA DNA typing and Antibody Profile**

Sl. No.	Amendment Request / Queries raised by the prospective bidders	Original Technical Specifications	Amended Technical Specification (NOTIFICATION NUMBER 5030 DTD 22/07/2024 )	Corrigendum Against Amendment
1	<p>1) In the price evaluation process, you have considered 100 tests per month for each test parameters. In any realistic scenario, number of tests for PRA Screening and Percentage tests, single Antigen Bead, MIC A, KIR, Non-HLA, DSA etc. are significantly less compared to HLA typing tests, in all transplant diagnostics institutes. But the prices for these kits are much higher than the typing kits. (For an example, when a lab has sample load of 100 typing per month; PRA and single Antigen load may be estimated as 30 no and 8 no per month respectively. But again, single Antigen kits price is three times of the HLA typing tests). We propose lesser numbers should be incorporated for all tests other than HLA typing tests. Otherwise only these tests kits prices would be deciding factor for this tender.</p> <p>2) When our competitor does not have DSA kit and Non-HLA kits, what price they are going to quote in the "Prices for Reagents and consumables" Part II Price Bid"? They might quote any less significant price for any kits which performance is not at a level of DSA Kits or if they quote zero value for this item, automatically they will get price benefit for this item. We propose not to consider this test in the evaluation.</p> <p>3) Immucor Non-HLA Kit antibody has coverage of 60 antigens, but our competitor does not have Non-HLA Antibody kit of this standard. Their Non-HLA Antibody kits may have very smaller number of antigens with significantly lesser kit cost. But the cost of this test is highest among all kits in this tender. Also, the requirement of this test is not very significant number in India scenario. We propose to remove this item or not to consider this test in the evaluation process. otherwise, Non-HLA Antibody test kits prices, which non-significant number in present scenario, would be deciding factor for this tender, being the highest value kit.</p>	<p><b>Test parameters as per Format-A (Price of Reagent/Consumables):</b></p> <ol style="list-style-type: none"> <li>HLA SSO DNA Typing</li> <li>Donor Specific Antibody</li> <li>Complement Dependent Cytotoxicity (C D C) for Cross match</li> <li>Virtual Cross match</li> <li>HLA Match</li> <li>HLA Panel Reactive Antibody (PRA) Antibodies</li> <li>HLA Single Antigen</li> <li>KIR Genotyping</li> </ol>	<p><b>Amended as:</b> The Price break up of all individual reagents / consumables required for performing the below mentioned tests (for 100 nos. of sample per month) must be mandatorily quoted in the separate PDF format (Format-A) of the financial bid (attached as a PDF file) in the e-tender portal, which shall be taken into account for price evaluation and shall be approved &amp; valid for 5 years from date of approval. <b>The below mentioned reagents should be USFDA OR CE-IVD approved:</b></p> <ol style="list-style-type: none"> <li>HLA Typing A</li> <li>HLA Typing B</li> <li>HLA Typing C</li> <li>HLA Typing DRB1</li> <li>HLA Typing DRB345</li> <li>HLA Typing DP</li> <li>HLA Typing DQ</li> <li>CDC Crossmatch</li> <li>PRA Antibody Screening Class I &amp; II</li> <li>PRA Percentage Class I &amp; II</li> <li>Single Antigen Bead Class I</li> <li>Single Antigen Bead Class II</li> </ol> <p><b>And</b> <b>The below mentioned reagents should be USFDA OR CE-IVD approved OR RUO(Research Use Only) Kit :</b></p> <ol style="list-style-type: none"> <li>KIR Genotyping</li> <li>MIC A Antibody</li> <li>Non HLA Antibody</li> <li>Donor Specific Antibody (DSA)</li> </ol>	<p><b>Amended as:</b> The Price break up of all individual reagents / consumables required for performing the below mentioned tests (for 100 nos. of sample per month) must be mandatorily quoted in the separate PDF format (Format-A) of the financial bid (attached as a PDF file) in the e-tender portal, which shall be taken into account for price evaluation and shall be approved &amp; valid for 5 years from date of approval. <b>The below mentioned reagents should be USFDA OR CE-IVD approved:</b></p> <ol style="list-style-type: none"> <li>HLA Typing A</li> <li>HLA Typing B</li> <li>HLA Typing C</li> <li>HLA Typing DRB1</li> <li>HLA Typing DRB345</li> <li>HLA Typing DP</li> <li>HLA Typing DQ</li> <li>CDC Crossmatch</li> <li>PRA Antibody Screening Class I &amp; II</li> <li>PRA Percentage Class I &amp; II</li> <li>Single Antigen Bead Class I</li> <li>Single Antigen Bead Class II</li> </ol> <p><b>And</b> <b>The below mentioned reagents are removed from the technical specification and the bidder should not quote the price of below reagents in the separate PDF format (Format A) of the financial bid :</b></p> <ol style="list-style-type: none"> <li>KIR Genotyping</li> <li>MIC A Antibody</li> <li>Non HLA Antibody</li> <li>Donor Specific Antibody (DSA)</li> </ol> <p><b>N.B:</b> a) Donor specific Antibody can be performed through single Antigen Bead class- I &amp; single Antigen Bead Class-II. b) The HLA crossmatching can be performed through CDC crossmatch and Fluoro Analyzer.</p>

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<p>2 Acceptance of the RUO Kits over IVD-approved reagents undermines the quality and safety standard norms that should be upheld in the procurement process. It is imperative that OSMCL adheres to the highest standards of the procurement practices and in compliance with regulatory standards recommended by DGHS, CDSCO, Government of India, to ensure the best outcomes for the healthcare system and the patients it serves.</p> <p>We strongly urge &amp; believe that immediate corrective measures only will help to restore confidence in the procurement process and ensure that OSMCL procures the highest quality products for its healthcare needs. We look forward to your prompt action to address our concerns and ensure a fair and transparent procurement process to make the state of art setup the HLA Laboratory, Transplant diagnostics at SCB Medical College, Cuttack.</p>			
<p>3 Acceptance of the RUO Kits over IVD-approved reagents undermines the quality and safety standard norms that should be upheld in the procurement process. It is imperative that OSMCL adheres to the highest standards of the procurement practices and in compliance with regulatory standards recommended by DGHS, CDSCO, Government of India, to ensure the best outcomes for the healthcare system and the patients it serves.</p> <p>We strongly urge &amp; believe that immediate corrective measures only will help to restore confidence in the procurement process and ensure that OSMCL procures the highest quality products for its healthcare needs. We look forward to your prompt action to address our concerns and ensure a fair and transparent procurement process to make the state of art setup the HLA Laboratory, Transplant diagnostics at SCB Medical College, Cuttack.</p>	<p>Additional point</p>	<p><b>Amended as:</b> All the Reagents/Consumables asked in the Format-A of the price bid should be USFDA OR CE- IVD approved except for the below mentioned reagents for which RUO (Research Use Only) kits are allowed, <b>(i) KIR Genotyping</b> <b>(ii) MIC A Antibody</b> <b>(iii) Non HLA Antibody</b> <b>(iv) Donor Specific Antibody (DSA)</b></p>	<p><b>Amended as:</b> All the Reagents/Consumables asked in the Format-A of the price bid should be USFDA OR CE- IVD approved. <b>The RUO (Research Use Only) kits are not allowed.</b></p> <p>The below mentioned reagents are removed from the technical specification and the bidder should not quote the price of below reagents in the separate PDF format (Format A) of the financial bid : <b>(i) KIR Genotyping</b> <b>(ii) MIC A Antibody</b> <b>(iii) Non HLA Antibody</b> <b>(iv) Donor Specific Antibody (DSA)</b></p>

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