# Application for inclusion of cardiac biomarker assay

The Committee on Clinical Applications of Cardiac Biomarkers (C-CB) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) invites manufacturers to submit applications for the inclusion of their **cardiac troponin** (cTn) or **natriuretic peptide** (NP) assays in the IFCC analytical tables (<https://ifcc.org/ifcc-education-division/emd-committees/committee-on-clinical-applications-of-cardiac-bio-markers-c-cb/biomarkers-reference-tables/>). The main intention of these tables is to provide an overview of assays from different manufacturers as described by the corresponding package inserts.

cTn and NP assays must meet the following criteria:

1. The company responsible for the assay needs to be a member of the IFCC and a corresponding member of the IFCC C-CB. Corresponding members do not have to attend the meetings or communicate with the C-CB if they do not wish to but could serve as a contact person only, being responsible for communicating with the IFCC C-CB and provide regular update of the information presented in the tables.
2. Only assays that are used internationally and have been cleared by a major governmental body like the American Food and Drug Administration, the Chines National Medical Products Administration, Japanese Pharmaceutical and Medical Device agency, European Commission or a similar national or overarching approval body of in vitro diagnostic instruments may be included in the list.
3. The information posted in the tables are the sole responsibility of the manufacturer of the assay. The manufacturer should fulfill the information enlisted in the tables (table 1 in the case of cTn assays, table 2 for NP assays and table 3 for both assays) and provide documentation, highlighting the relevant information.
4. The documentation provided by the manufacturer should correspond in the information provided in the package insert of the assay. If this is not present a peer reviewed publication from an international journal might serve as documentation until the package insert is updated.
5. To be enlisted as a high-sensitivity cTn (hs-cTn) assay, manufacturers must provide at least:
	* The limit of detection (LoD) of the assay and the percentage of healthy individuals with detectable concentrations (at least 50%, both sexes).
	* The sex-specific 99th percentile and number of individuals included in the study (>400 females and 400 males for assays approved after 2024 or >300 females and 300 males for assays approved from 2018-2024).
	* The concentration with a coefficient of variation (CV) of 10% or the CV at the 99th percentile (<10%).

All applications should be submitted electronically via email to kristin.moberg.aakre@helse-bergen.no with the subject line: “Application for inclusion of cardiac biomarker assay.” Submissions will go through internal review by the IFCC C-CB members before being posted. For inquiries or further assistance, please contact: Professor Kristin M Aakre (kristin.moberg.aakre@helse-bergen.no), University of Bergen. We look forward to your submissions and appreciate your contributions to advancing the field of cardiac biomarker assays.

## Table 1. Cardiac troponin assays

|  |  |  |
| --- | --- | --- |
| **Manufacturer information** | **Information** |  |
| Company |  | - |
| Platform |  | - |
| Assay |  | - |
| Contact person |  | - |
| Contact email |  | - |
| **Analytical characteristics table** | **Information** | **Reference\* (paragraph, page)** |
| LoB (Include unit; ng/L or μg/L) |  |  |
| LoD (Include unit; ng/L or μg/L) |  |  |
| CV (%) at 99th percentile(Overall, M/F) | Overall:M:F: |  |
| Concentration at 20% CV (Include unit; ng/L or μg/L) |  |  |
| Concentration at 10% CV (Include unit; ng/L or μg/L) |  |  |
| Reference population (n, age)(Overall, M/F) | Overalln =Age (years) =Mn =Age (years) =Fn =Age (years) = |  |
| 99th percentile (Include unit; ng/L or μg/L)(Overall, M/F) | Overall:M:F: |  |
| Specimen type |  |  |
| Normals measured ≥ LoD (%)(Overall, M/F) | Overall:M:F: |  |
| Statistic used to calculate 99th Percentile (robust/non-parametric) |  |  |
| Calibrator material |  |  |
| Epitopes recognized by antibodies |  |  |
| County of Package Insert: version date |  |  |
| **Interference table** | **Information** | **Reference\* (paragraph, page)** |
| Hemolysis | Hemolysis limit (no interference up to stated value) |  |  |
| Influence of hemolysis above the threshold (+/-) |  |  |
| End user hemolysis assessment |  |  |
| Acceptance criteria |  |  |
| Biotin | Biotinylated antibody |  |  |
| Biotin used in assay configuration |  |  |
| Interference threshold |  |  |
| Acceptance criteria |  |  |
| Highest biotin concentration on tested |  |  |
| Influence of biotin above the threshold |  |  |

CV: coefficient of variation; F: females; LoB: limit of blank; LoD: limit of detection; M: males.

Reference\*: Please state the package insert number and country/region and approval body. Publications may be used for single items only, please provide the reference of the publication as applicable.

## Table 2. Natriuretic peptide assays

|  |  |  |
| --- | --- | --- |
| **Manufacturer information** | **Information** |  |
| Company |  | - |
| Platform |  | - |
| Assay |  | - |
| Contact person |  | - |
| Contact email |  | - |
| **Analytical characteristics table** | **Information** | **Reference\* (paragraph, page)** |
| LoD (ng/L) |  |  |
| CV (%) near LoD or LoQ (concentration, ng/L) |  |  |
| URL (ng/L)(if possible, by age) |  |  |
| CV (%) at URL |  |  |
| Reference intervals by sex (ng/L) |  |  |
| Reference Intervals by age/sex (median in ng/L, n) |  |  |
| Specimen type |  |  |
| Capture antibody |  |  |
| Detection antibody |  |  |
| Standard material |  |  |
| Point-of-care Testing assay (yes/no) |  |  |
| County of Package Insert: version date |  |  |
| **Interference table** | **Information** | **Reference\* (paragraph, page)** |
| Hemolysis | Hemolysis limit (no interference up to stated value) |  |  |
| Influence of hemolysis above the threshold (+/-) |  |  |
| End user hemolysis assessment |  |  |
| Acceptance criteria |  |  |
| Biotin | Biotinylated antibody |  |  |
| Biotin used in assay configuration |  |  |
| Interference threshold |  |  |
| Acceptance criteria |  |  |
| Highest biotin concentration on tested |  |  |
| Influence of biotin above the threshold |  |  |

CV: coefficient of variation; F: females; LoD: limit of detection; LoQ: limit of quantification; M: males; URL: Upper Reference Limit

Reference\*: Please state the package insert number and country/region and approval body. Publications may be used for single items only, please provide the reference of the publication as applicable.

Table 3. Inclusion criteria checklist

|  |  |
| --- | --- |
| **Point** | **Yes/no** |
| The company responsible is a member of the IFCC and a corresponding member of the IFCC C-CB |  |
| The assay is cleared by a governmental body of IVD instruments (include which body the applicable package insert is approved by) |  |
| The manufacturer provides documentation for the data enlisted in the tables, highlighting the relevant information |  |
| The main documentation provided by the manufacturer is corresponding to the information in the package insert (publication from an international journal or congress may be used until the package insert is updated) |  |
| *Only for hs-cTn*. The percentage of health individuals with detectable concentrations is at least 50% (both sexes). |  |
| *Only for hs-cTn*. The study design for the sex-specific 99th percentile is appropriate. |  |
| *Only for hs-cTn*. The CV at the 99th percentile is ≤10%. |  |

CV: coefficient of variation; hs-cTn: high-sensitivity cardiac troponin; IVD: In vitro diagnostic