**Part 1: Laboratory**

|  |  |
| --- | --- |
| 1. Name of the laboratory or institute |  |
| 2. Date of receipt of the samples |  |
| 3. Date of the analysis of the samples |  |

**Part 2: Results**

Please fill in the results of the analysis. There are two result pages because all samples are provided on two different sampling cards. Please take care to fill in the appropriate table.

**Whatman FTA DMPK-C cards**

|  |  |
| --- | --- |
| **Sample name** | **Result** |
| Sample C1: Ciclosporin A in µg/L |  |
| Sample C2: Ciclosporin A in µg/L |  |
| Sample C3: Ciclosporin A in µg/L |  |
| Sample T1: Tacrolimus in µg/L |  |
| Sample T2: Tacrolimus in µg/L |  |
| Sample T3: Tacrolimus in µg/L |  |
| Creatinin in µmol/L |  |
| Hematocrit in (v/v) |  |

**Whatman 903 paper**

|  |  |
| --- | --- |
| **Sample name** | **Result** |
| Sample C1: Ciclosporin A in µg/L |  |
| Sample C2: Ciclosporin A in µg/L |  |
| Sample C3: Ciclosporin A in µg/L |  |
| Sample T1: Tacrolimus in µg/L |  |
| Sample T2: Tacrolimus in µg/L |  |
| Sample T3: Tacrolimus in µg/L |  |
| Creatinin in µmol/L |  |
| Hematocrt in (v/v) |  |

**Part 3: Analysis**

|  |  |
| --- | --- |
| 1. Type of method used?(circle correct answer) | HPLC / LC-MS / LC-MS-MS / Immunosassay / GC-MS / UPLC / UPLC and LC-MS-MS / different, namely |
| 2. Punchsize in mm ( or when using wholespot analysis, state here)? | …. mm |
| 3. Optional: Type of device used for punching (provide specifications)? |  |
| 4. What internal standard is used for analysis? | Tacrolimus: Cyclosporin A: Creatinin: |
| 5. When is the internal standard added during analysis? (circle correct answer) | On the spot / During extraction / after extraction / Different, namely ….. |
| 6. Please briefly describe the extraction method used for DBS or provide a literature reference. | (Example: punch 3 mm 🡪 add methanol/water 80:20 🡪 vortex 🡪 sonicate 🡪 vortex 🡪 inject in LCMS) |
| 7. How many QC samples were added and at what level (e.g. low/med/high)? | Tacrolimus: Cyclosporin A: Creatinin: |
| 8. How are the QC samples prepared? (circle correct answer) | Self-made using fresh blood / bought / different, namely … |
| 9. What is the analytically validated range for Tacrolimus? | From … µg/L to … µg/L |
| 10. What is the analytically validated range for Ciclosporin A? | From … µg/L to … µg/L |
| 11. Optional: what is the analytically validated range for creatinin? | From … µmol/L to … µmol/L |
| 12. What type of paper was used during the analytical validation of the method? | Whatman DMPK-C / Whatman 903 / Whatman DMPK-A / Agilent Elud / Different, namely …. |

**Part 4: Clinical application**

|  |  |
| --- | --- |
| **Sample name** |  |
| 1. Is the DBS method to measure immunosuppresants used in clinical practice by patients? (when answered no, please skip of part 4) | Yes / No |
| 2A. Is the DBS analysis method clinically validated with a patient study performed in your hospital/centre?\* (When answered yes, please answer questions 2 B,C,D. When answered no, please answer question 2E) | Yes / No |
| 2B. What is the clinically validated range for Tacrolimus?\* | From … µg/L to … µg/L |
| 2C. What is the clinically validated range for Cyclosporin A?\* | From … µg/L to … µg/L |
| 2D. What is the clinically validated range for creatinin?\* | From … µmol/L to … µmol/L |
| 2E. Do you use a clinically validated range provided in literature or by another laboratory? (When answered yes, please provide a reference) | Yes / No |
| 3A. Do you correct the results of DBS analysis of tacrolimus and cyclosporine A for hematocrit? (if answered yes, please answer question 3B) | Yes / No |
| 3B. Please briefly describe the method used for hematocrit correction or provide a literature reference. |  |
| 4. Optional: Do you use a correction factor or conversion formula to calculate creatinin levels? (When answered yes, please provide the formula) |  |
| 5. What type of paper is used in clinical practice by patients? | Whatman DMPK-C / Whatman 903 / Whatman DMPK-A / Agilent Elud / Different, namely …. |

\* A clinical validation study is a study where paired patient samples (DBS and reference wholeblood/serum samples) are obtained from a group of patients and analyzed. The results are compared using appropriate statistical tests. This range can be different from an analytical validation range which is usually broader. For instance: Tacrolimus analytical range can be 1.0 – 100.0 µg/L. If, during a clinical validation study, only paired samples of 1.0 µg/L – 30.0 µg/L are collected the clinical validation range will be 1.0-30.0 µg/L.

If you have any questions or remarks, please let us know below

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