

## TAP II Analyte Compatibility (CE)

- The labeled intended purpose of the TAP II Blood Collection Device is:

*The TAP II Blood Collection Device is used to collect capillary blood for tests requiring a small amount of blood. Capillary blood should be obtained from adults (21 years of age or older). Samples can be used for testing using systems that accept serum or blood anticoagulated with lithium heparin. The TAP II Blood Collection Device can be used by a layperson or healthcare worker.*

- YourBio Health has validated that TAP II samples give equivalent results to venous samples for the following analytes:
  - Hemoglobin A1c
  - Total Cholesterol
  - HDL-Cholesterol
  - LDL-Cholesterol
  - Triglycerides
  - Anti-SARS-CoV-2 Antibodies
- In general, we expect that TAP II samples will be suitable for any application for which fingerstick capillary specimens are acceptable.
- Limitations:
  - Some analytes are known to differ in concentration between capillary and venous blood (e.g., glucose, blood gases)
  - The TAP II device collects a high-quality sample, with low hemolysis (< 50 mg/dL), but TAP II samples might not be suitable for analytes with stringent hemolysis requirements
  - The TAP II device is not currently available in EDTA or Citrate versions, so cannot be used for analytes requiring those additives (some haematology parameters, some DNA applications, coagulation)
- For applications involving sample shipping to a laboratory, stability of the analyte in whole blood at ambient temperatures will be an important consideration
- Third parties have published data on the use of TAP II for the following analytes:
  - Anti-SARS-CoV-2 antibodies <sup>1-3</sup>
- Third parties have published data on the use of TAP (a first generation device based on same microneedle technology) for the following analytes:
  - anti-Mullerian hormone (AMH) <sup>4</sup>
  - cholesterol, HDL <sup>5</sup>

- cholesterol, LDL <sup>5</sup>
  - cholesterol, total <sup>5</sup>
  - cortisol <sup>5</sup>
  - creatine kinase <sup>6</sup>
  - insulin-like growth factor 1 <sup>7,8</sup>
  - metabolomics (amino acids, glycolytic/krebs cycle intermediates) <sup>9</sup>
  - microRNA markers of blood doping <sup>10</sup>
  - protein biomarkers <sup>11</sup>
  - sex hormone binding globulin (SHBG) <sup>5</sup>
  - single-cell sequencing <sup>12</sup>
  - testosterone <sup>5</sup>
  - thyroid stimulating hormone (TSH) <sup>5</sup>
- YourBio Health has received unpublished reports of evaluations of TAP and TAP II for several additional analytes

## References

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