



# IQVIA Laboratories Pediatric Drug Development Solutions

*Pediatric sample capabilities and special handling*

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More pharmaceutical clinical trial studies are enrolling pediatric subjects because they can respond to drugs differently than adults do. New drugs which are intended for use in a pediatric population must be tested and properly evaluated for use in pediatric patients. Evidence for pediatric efficacy and safety is required by the U.S. FDA under the Pediatric Research Equity Act. Pediatric clinical trials have unique challenges because they need to be adapted to meet children's needs as well as the families' needs. This is also relevant to the COVID-19 pandemic, where a significant increase in the incidences of Kawasaki-like disease symptoms is being observed in pediatric populations

Obtaining quality samples with enough volume for testing from very young pediatric subjects can be difficult, and tests are often cancelled when very low volume samples are received in a clinical laboratory. Furthermore,

We recognize the need to reduce the blood volume required in this population. Our mission is to treat each sample as if a life depends on it. We have established policies and procedures specifically tailored for pediatric sample collection, handling, and testing to ensure the best chance for reliable results on very low volume samples.

## Precise low volume blood sample requirements

It is often critical to minimize the volume of blood taken from very young pediatric subjects, especially in clinical trial studies where the subjects may have multiple blood draws over relatively short periods of time. Equally important is the need to reduce test cancellation due to insufficient volume, to avoid the need for a second blood draw. Our scientists have worked with our automated instrument vendors and our own laboratorians and instruments to take full advantage of the micro-sampling capabilities of our state- of-the-

art chemistry, immunochemistry, and hematology analyzers. We know exactly how much serum or whole blood is required to obtain accurate results from very low volume samples, which can help minimize overall blood volume requirements.

Experiments performed on our own instruments in our labs have demonstrated that we can obtain accurate and reliable results for a typical 20-analyte chemistry panel from as little as 500  $\mu$ L (0.5 mL) of serum, or an accurate Complete Blood Count (CBC) result from the same volume of K<sub>2</sub>EDTA whole blood. We also know what results can be obtained on lower volume samples and how to optimize testing on those samples. We have developed a unique 12-analyte short-sample chemistry panel that our labs can easily refer to when we receive sub-optimal serum volume samples for chemistry panels with more analytes.

## Short-sample chemistry panel

The short-sample chemistry panel is pre-defined to include all chemistry analytes that could potentially have a critical value as well as liver and kidney function safety markers. Only analytes in protocol will be tested and reported. This option is available for pediatric subjects younger than 6 years old, when low volume samples are submitted to the laboratory in a 2.0 mL graduated vial

with special handling of these irreplaceable samples by both specimen processing and laboratory staff. If there is insufficient volume for the chemistry panel ordered, the short-sample chemistry panel option is chosen. A similar option is available for hematology/CBC samples, where trained laboratorians know when to manually manipulate a very low volume sample to obtain accurate CBC results, if needed.

Standardized SOPs used globally across our labs for routine testing detail any special handling needed for low volume pediatric samples. Both chemistry and immunochemistry samples can be transferred to specifically designed micro sample cups that, together with special instrument programming, minimize the dead volume required on automated instruments to obtain accurate results.

Recommended minimum blood volumes by age group

PATIENT AGE GROUP	CHEMISTRY PANEL* (20 ANALYTES) WHOLE BLOOD	CHEMISTRY PANEL* (20 ANALYTES) SERUM	HEMATOLOGY	TOTAL WHOLE BLOOD VOLUME
<2 years old	1.1 mL	0.5 mL**	0.6 mL	1.7 mL
2 to 6 years old	2.6 mL	1.1 mL	1.2 mL	3.8 mL
>6 years old	3.5 mL	1.4 mL	2.0 mL	5.5 mL

\*Routine serum safety chemistries only — additional tests like thyroid, sex, or growth hormone markers may require additional serum.  
\*\*Minimum volume requirement — may not be enough to repeat/confirm abnormal results.

Urinalysis and pediatric samples

We have created a unique test code for very low volume pediatric urine samples, that includes a unique ‘volume check code’ to be ordered for any pediatric urinalysis testing for subjects <5 years old. We also have special Peds labels to help our labs identify these special samples. The optimum urine volume for adults is 10 mLs for both Macroscopic and Microscopic Urinalysis, and the minimum volume needed for our routine automated systems is 5 mLs.

For pediatric samples, all IQVIA Laboratories central labs have agreed they can test the following minimum volumes:

- For Macroscopic, 1 mL urine minimum (labs need to use manual procedure to apply urine to test strips and read manually)
- For Microscopic, 2 mL urine minimum (labs need to use manual microscopy)

If <5 mLs total, a comment will be added to the reports:

*“Less than optimal volume collected for microscopic urinalysis; review results in context with clinical findings.”*

Infant pediatric urine bag supplies and instructions are available for non-potty-trained subjects.



## Specialized blood collection supplies for pediatric subjects

We have designed pediatric-specific blood collection kits and supplies based on specific age groups to aid in the successful collection of pediatric samples. The Sarstedt Monovette system combines the control provided by a syringe with the clot activators and/or anticoagulants commonly available in evacuated blood tubes. Because the Monovette system allows for gentle blood collection using a controlled aspiration technique, it is the ideal solution for difficult vein conditions in pediatrics.

Used in combination with a winged infusion set and 23-gauge needle (see photo), this combination allows the best chance of success in difficult pediatric draws.

## Advantages of using Sarstedt Monovette® tubes

Traditional vacuum blood draw tubes can have too much vacuum for many pediatric subjects' veins. Using the plunger-equipped Monovettes is like using a traditional syringe — the phlebotomist can control the vacuum and continue filling the tube if blood flow is interrupted. The ability of these tubes to enable gentle aspiration of blood makes the Monovette the ideal solution for difficult vein conditions in pediatric patients. Unlike traditional syringes, non-SST Monovette tubes contain anticoagulants that mix with the blood while filling, minimizing the chance of clot formation. Different Monovette tubes can be exchanged during one blood draw using the locking luer adapter at the end of the Sarstedt Safety-Multifly® 23g needle infusion set.

Once the blood sample has been collected, the plunger is snapped off and the tube can be centrifuged, and serum or plasma separated if required.



### RECOMMENDED PEDIATRIC BLOOD DRAWING SUPPLIES (PEDIATRIC SUBJECTS <6 YEARS OLD)

**CHEMISTRY:** Sarstedt Monovette 1.1 mL serum gel (use two for 2.2 mLs)

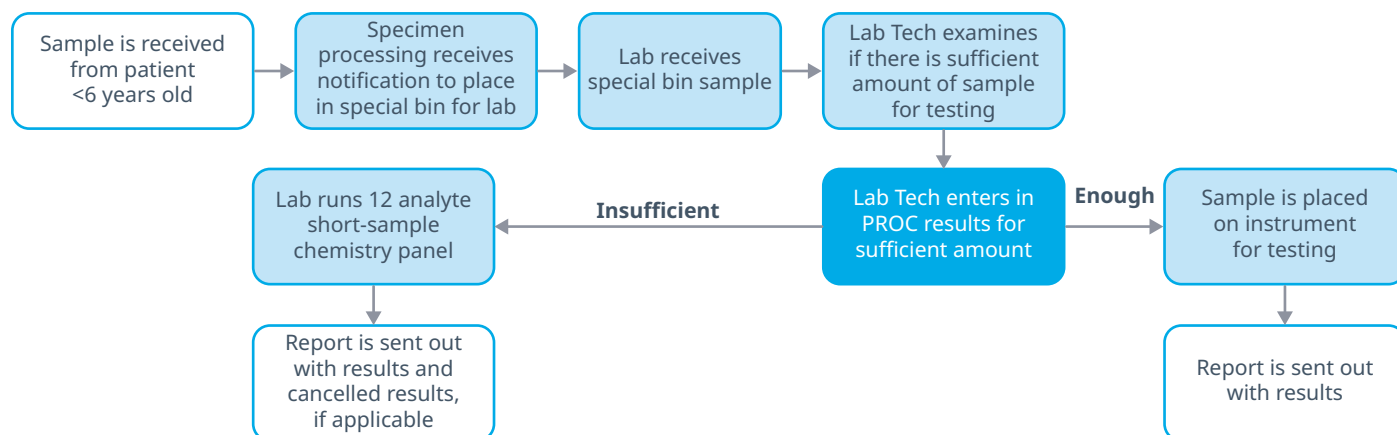
**HEMATOLOGY:** Sarstedt Monovette 1.2 mL K<sub>2</sub> EDTA (lavender)

Also available: 500 µL BD EDTA MAP (250 – 500 µL) — if lower blood volumes desired for CBC





## Short sample chemistry panel



**12 Analyte short-sample chemistry\*:** Albumin, T Protein, Glucose, Sodium, Potassium, Chloride, Magnesium, Calcium, Phosphorus, Total Bilirubin, ALT and Creatinine. \*All chemistry analytes with potential critical values are part of this panel. Any analyte not in protocol will not be tested or reported.

## Pediatric study set-up and age-specific blood collection kits

Any new clinical trial studies with pediatric subjects under 6 years old will be set up with a special procedural code that will prompt for special handling of serum samples submitted for safety panel chemistry tests. Specially trained laboratory staff will determine whether enough serum exists to obtain reliable results on the chemistry panel ordered; if there is not, they will activate

the short-sample chemistry panel described above. Similar special handling will be used for low volume CBC samples to assure the successful processing and testing of these irreplaceable samples. A nominal fee will be added to cover the extra manual labor associated with this special handling. Age-specific blood draw kits are configured based on pediatric subject age (<2 years, 2-6 years, and 6-12 years) with blood drawing supplies configured to optimize and minimize the amount of blood drawn based on the age group and test mix or complexity.

***Blood collection kits for pediatric <6 years old will be supplied with special low volume aliquotting transport tubes and transfer pipettes***



**2.0 mL Transport Vial (with 0.25 mL graduations)**

Image courtesy of Sarstedt, Inc.



**Transfer Pipette (with 0.1 mL [100 µL] graduations)**



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