

Optimizing Thermal Management in the Atellica CI Analyzer Using Computational Fluid Dynamics for Reducing Assay Bias

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Background

Ambient temperature fluctuations can significantly influence performance of immunoassays (IA), disrupting reaction kinetics and compromising repeatability of analyte measurements. Key areas affected include sample temperature, incubation temperature, wash ring temperature, and flash reaction temperature (see Figure 7). Sample temperature, which is not controlled by the system, can influence concentration due to density changes. Incubation temperature, controlled by the system, must be consistent to ensure reliable results. Wash ring temperature affects wash efficiency and particle retention, while flash reaction temperature impacts the chemiluminescent reaction output. Different assays are impacted to varying degrees by these temperature factors, with specific assays like BNP, DHEAS, CA19-9, DGTN, FER, PCT, and THCG being most sensitive to these changes. Siemens Healthineers addressed this issue with computational fluid dynamics (CFD) to predict heat transfer in the Atellica CI Analyzer. This virtual modeling guided layout of the subsystems placing them inside an isothermal envelope and facilitated hardware integration. Considering all thermal loads and cooling of the lower deck, the simulation guided optimal hardware layout and intra analyzer airflow, achieving a temperature range of $\pm 2^{\circ}\text{C}$ of the target mean to minimize assay bias under varying laboratory ambient and power electronics conditions.

Methods

STAR-CCM+ Tool

STAR-CCM+, a commercial CFD tool, was employed to simulate conjugate heat transfer, air distribution, and thermal performance of the Atellica CI Analyzer. The analyzer was modeled as two volumetric regions—the upper deck, housing assay-related reactions, and the lower deck, casing electronic control equipment, as shown in Figure 1. Both the upper and lower decks were modeled using a high-resolution computational mesh to capture all relevant thermal exchanges. Figure 2 shows a cross section of the mesh used to resolve conjugate heat transfer across air and solid regions. This level of detail was essential for ensuring a nearly isothermal upper deck, independent of ambient lab conditions and lower deck activity. The analyzer's flow was simulated as three-dimensional, turbulent, and steady. Turbulent flow around the Hydra instrument was modeled using the All y^+ wall treatment in STAR-CCM+, selected due to mesh limitations that prevented resolving the viscous sublayer and low flow velocities that made traditional low y^+ and high y^+ treatments inappropriate. Much of the analyzer exhibited mixed convection, where both forced and natural convection influenced heat transfer and airflow. Thermal boundary conditions included specified power inputs for all major components, such as pumps, solenoids, fan motors, and computers, as illustrated in Figure 3. Fans were modeled either by assigning 3D-scanned blade geometry to a Multiple Reference Frame (MRF) region—a standard CFD method for simulating rotating machinery—or by applying manufacturer-supplied flow-pressure curves. Cold air for cooling the lower deck was drawn in from the front doors, as shown in Figure 4.

Following the CFD analysis, physical engineering prototypes were built to support experimental assay characterization.

Atellica IM Ambient Temperature Effect Assay Verification Methods

The following assays were tested to evaluate the impact of ambient temperature on their performance: B-type natriuretic peptide (BNP), carbohydrate antigen 19-9 (CA19-9), digoxin (DGTN), dehydroepiandrosterone sulfate (DHEAS-SO4), ferritin (FER), prolactin (PCT), and total human chorionic gonadotropin (ThCG). These assays were selected based on their sensitivity to temperature variations during different stages of the analytical process. The experimental design assesses the impact of ambient temperature on assay performance using Siemens instrument platforms. Calibrators, controls, and patient samples are tested at three different ambient temperatures: the low (18°C) and high (30°C) ends of the instrument rating range, and a midpoint (24°C). The maximum allowable ambient temperature effect for individual samples is set at $\leq 15\%$, with a maximum mean percentage bias of $\leq 10\%$. The design verification involves using one reagent lot, one instrument, and running tests over three days at each temperature, with two levels of control product and five patient sample pools covering the measuring range and medical decision levels. Bias requirements are assessed individually for each assay, considering the Total Allowable Error at Medical Decision Levels.

Results (CFD)

The CFD-designed thermal control strategy for the IA engine-maintained performance within $\pm 2^{\circ}\text{C}$ of the setpoint across a range of laboratory ambient temperatures from 18°C to 30°C . Because the temperature setpoint was monitored at only two locations in the upper deck, achieving highly uniform airflow distribution was essential. This was accomplished using optimized baffles, which provided precise control of airflow within the upper deck.

To ensure sufficient heating of the wash pumps and their associated delivery lines, the IA heater was mounted vertically near the right panel of the upper deck, as shown in Figure 5. A specially tuned baffle was required to prevent overheating of components located directly below it by creating a thermal dead zone. This baffle featured two windows that directed airflow to critical areas, such as the wash pumps and the cuvette loader, while also maintaining balanced flow across the entire IA side of the instrument.

The CC airflow distributor provided heating along the front of the instrument, specifically along the path traveled by the sample probe assembly between aspiration and dispense, as illustrated in Figure 6. Figure 7 presents temperature difference contours in the upper deck between 30°C and 18°C ambient conditions. The objective was to minimize these temperature variations by adjusting heater power and relying on optimized airflow distribution, as previously described. Dark blue regions in the contour plots represent zero temperature difference, and most IA assay-critical components exhibited temperature variations of less than 2°C .

Figures 8 and 9 show the cooling airflow patterns in the lower deck. Although the cool air was drawn in from the front of the instrument, effective airflow was maintained throughout, including at the rear. This provided adequate cooling for high-power components such as the vacuum pump.

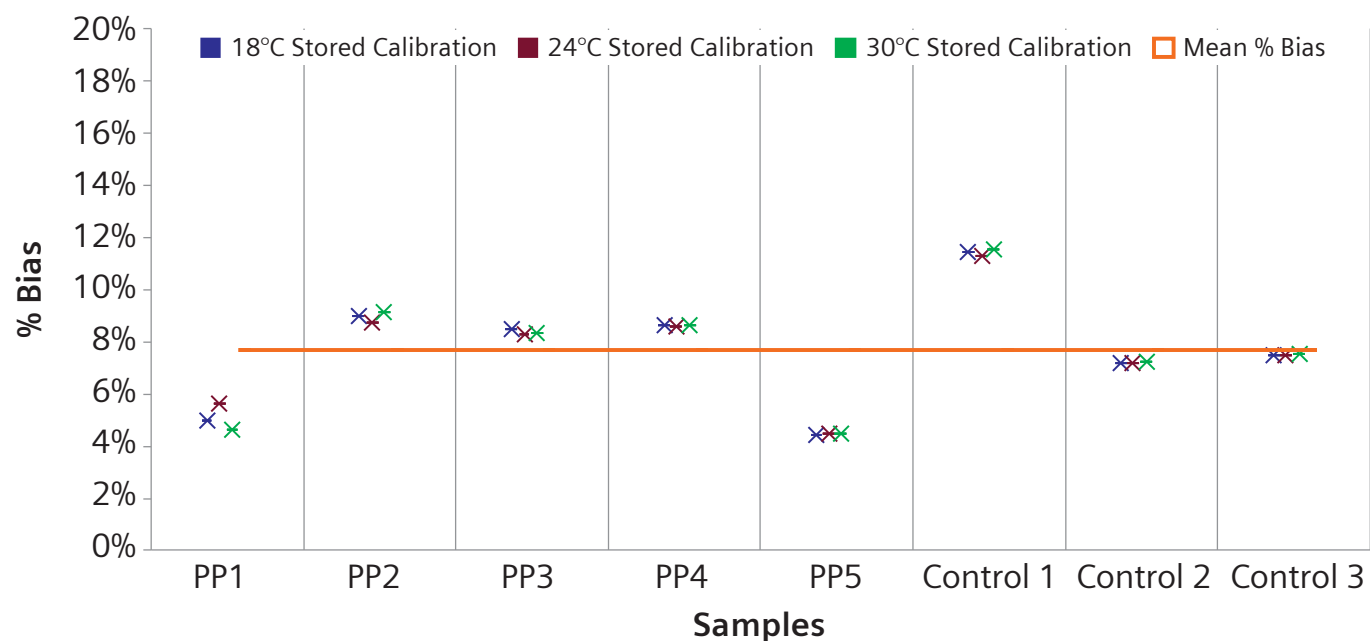
Results (Assay)

Summary of Assay Results:

BNP

Samples Tested: 5 contrived human EDTA plasma samples and 3 quality control samples.

Results: All samples passed the acceptance criteria with a maximum individual % Bias of 11.4% and a mean % Bias of 7.7%.

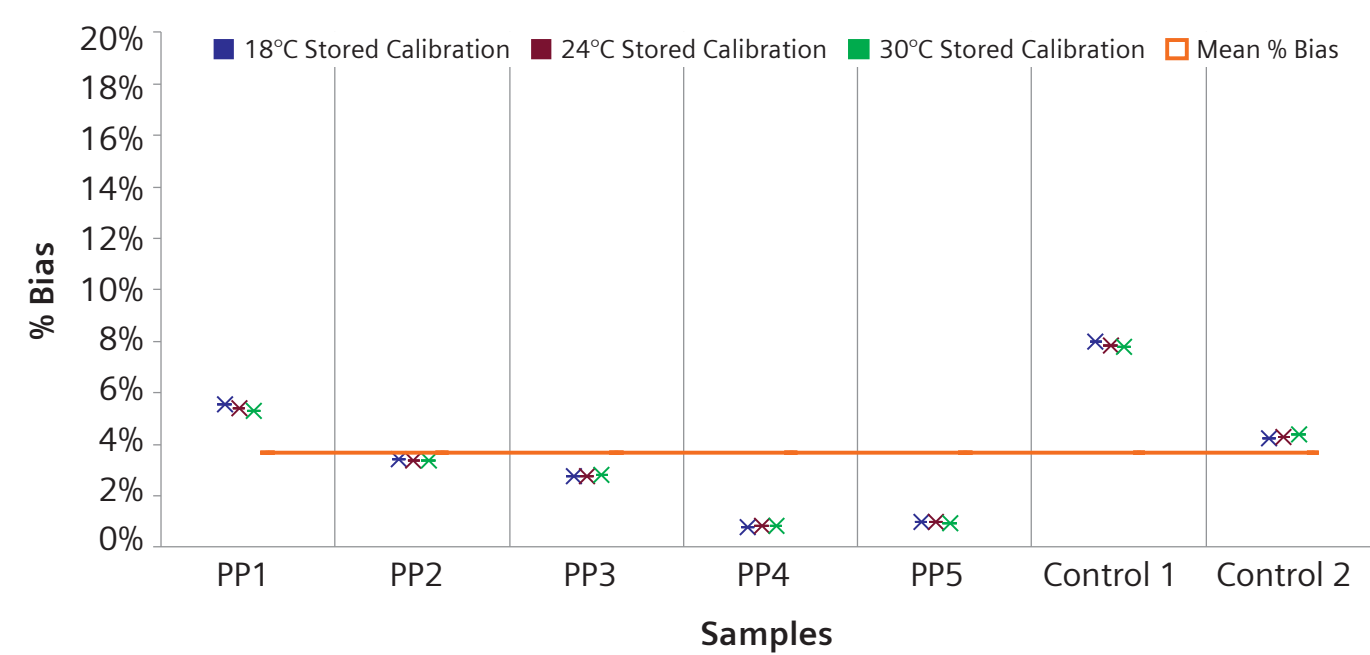


Ambient Temperature Effect on BNP Atellica IM Assay

CA19-9

Samples Tested: 5 contrived human serum samples and 3 quality control samples.

Results: All samples passed the acceptance criteria with a maximum individual % Bias of 8.0% and a mean % Bias of 3.7%.

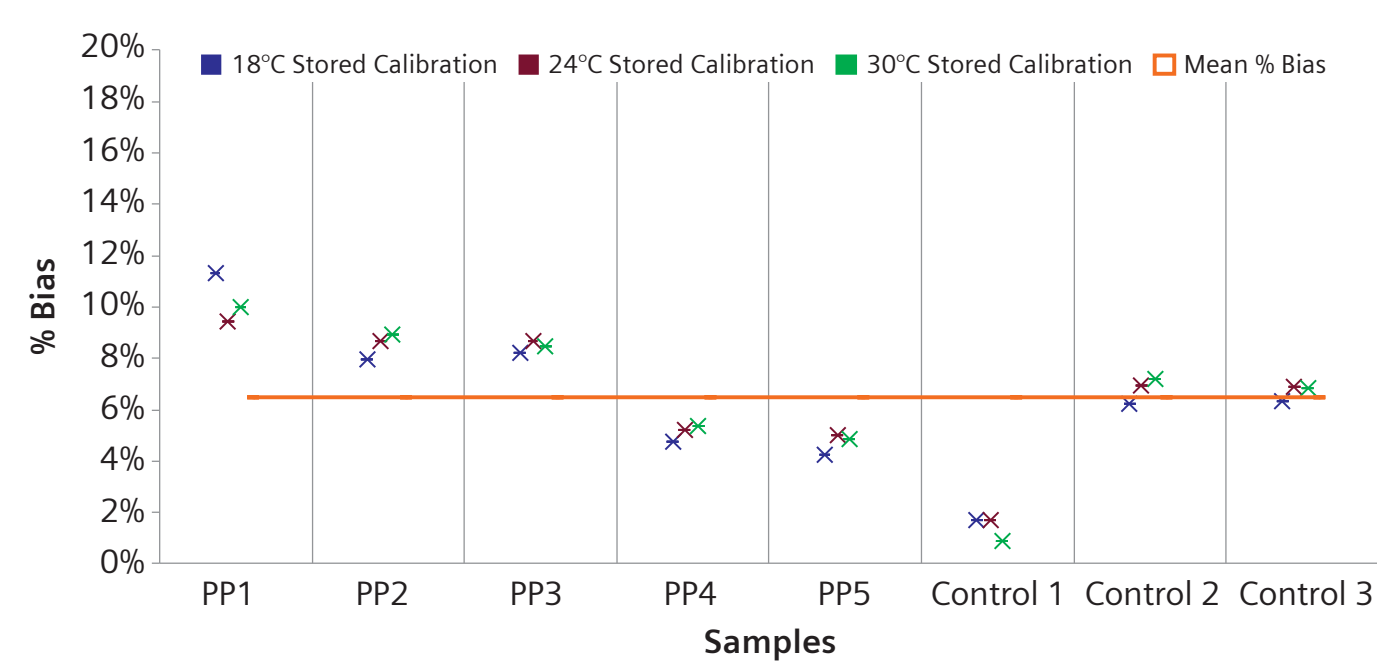


Ambient Temperature Effect on CA 19-9 Atellica IM Assay

Dgtn

Samples Tested: 5 contrived human serum samples and 3 quality control samples.

Results: All samples passed the acceptance criteria with a maximum individual % Bias of 11.3% and a mean % Bias of 6.3%.

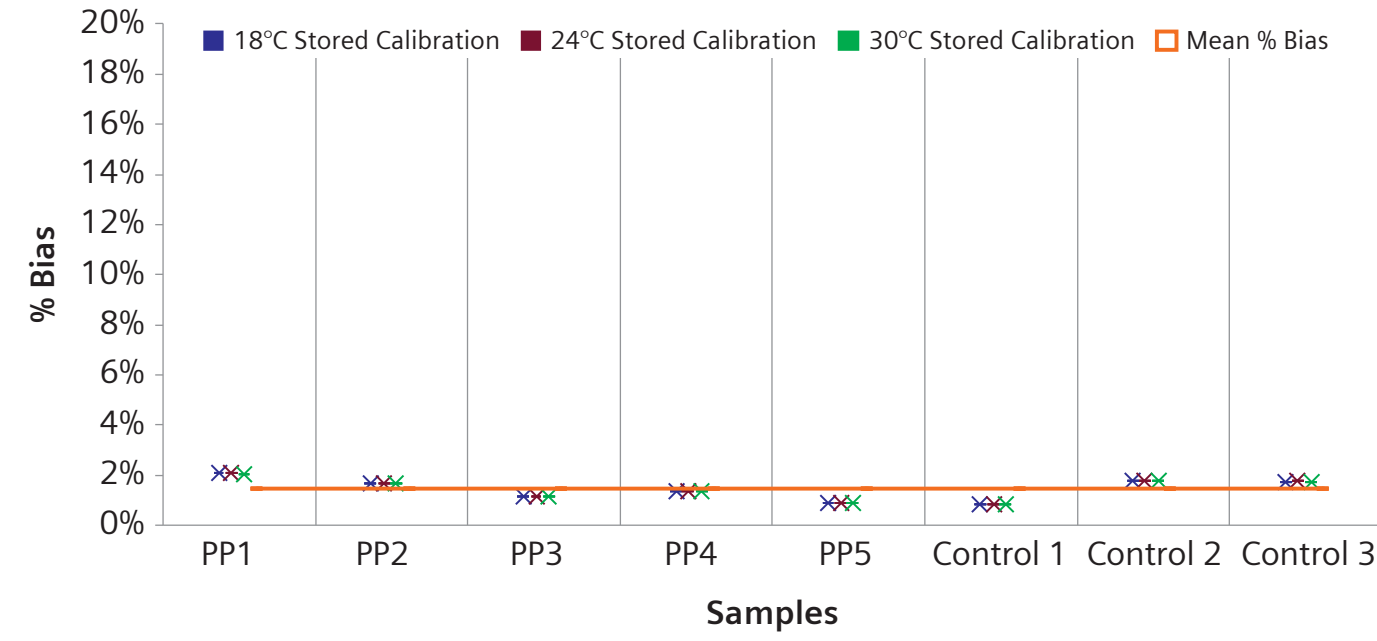


Ambient Temperature Effect on Dgtn Atellica IM Assay

DHEAS

Samples Tested: 1 native human sample, 4 contrived individual human serum samples and 3 quality control samples.

Results: All samples passed the acceptance criteria with a maximum individual % Bias of 2.1% and a mean % Bias of 1.4%.

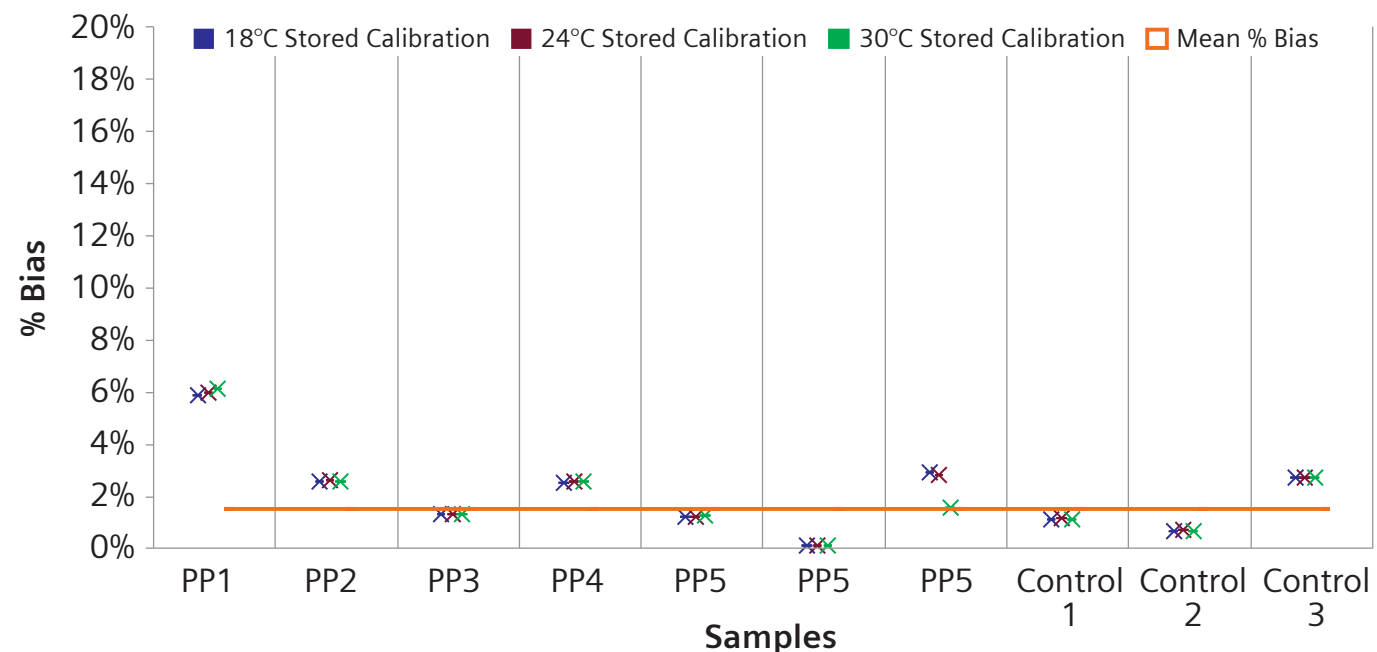


Ambient Temperature Effect on DHEAS-SO4 Atellica IM Assay

Fer

Samples Tested: 4 native human samples, 3 contrived individual human serum samples and 3 quality control samples.

Results: All samples passed the acceptance criteria with a maximum individual % Bias of 6.1% and a mean % Bias of 2.1%.

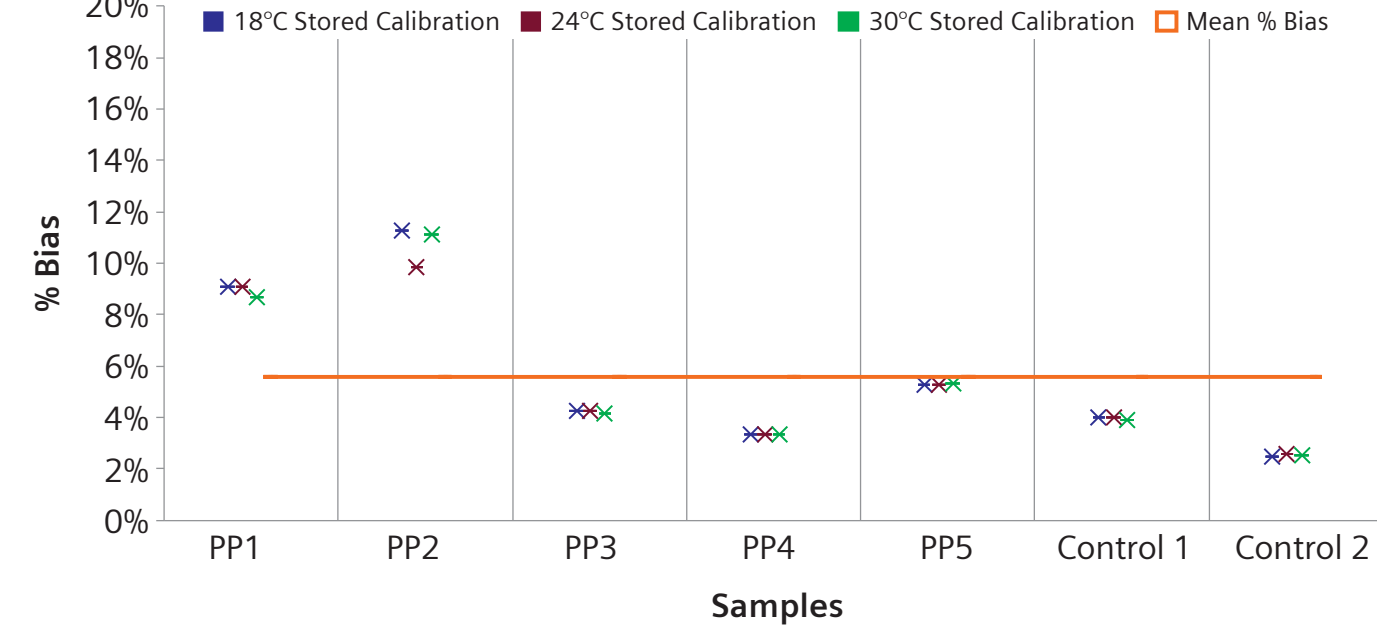


Ambient Temperature Effect on Fer Atellica IM Assay

PCT

Samples Tested: 5 contrived human serum samples and 2 quality control material.

Results: All samples passed the acceptance criteria with a maximum individual % Bias of 11.3% and a mean % Bias of 5.7%.

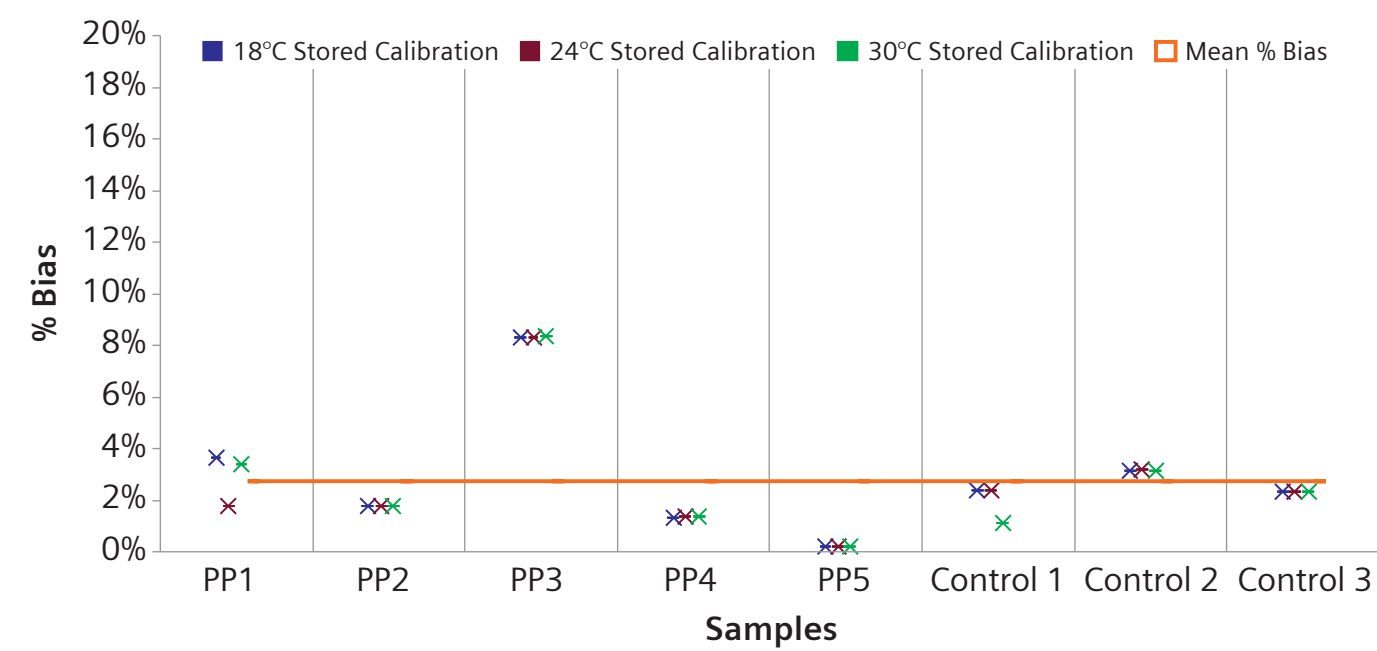


Ambient Temperature Effect on PCT Atellica IM Assay

ThCG

Samples Tested: 5 contrived human serum samples and three quality control material.

Results: All samples passed the acceptance criteria with a maximum individual % Bias of 8.4% and a mean % Bias of 2.9%.



Ambient Temperature Effect on ThCG Atellica IM Assay

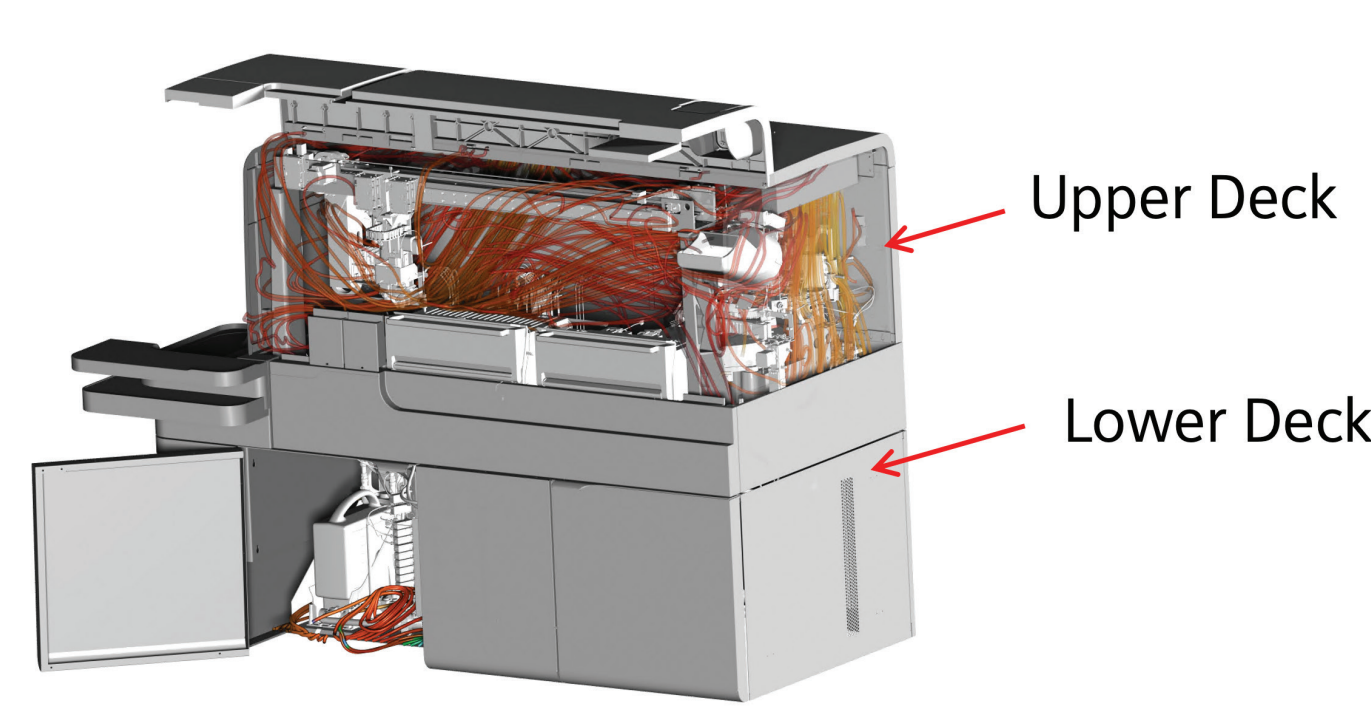


Figure 1: Location of the upper and lower decks

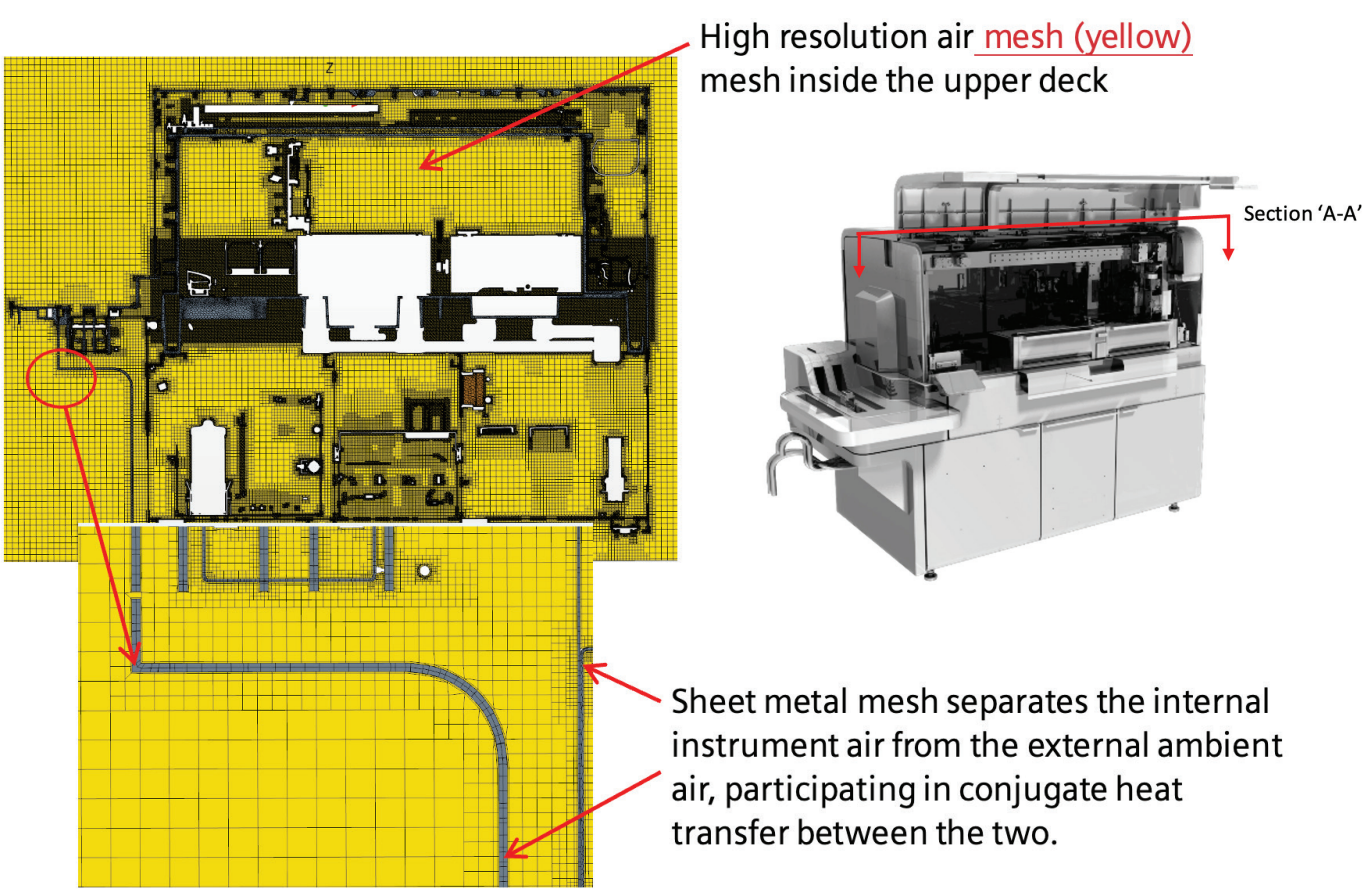


Figure 2: Illustration of the computational mesh (section 'A-A')

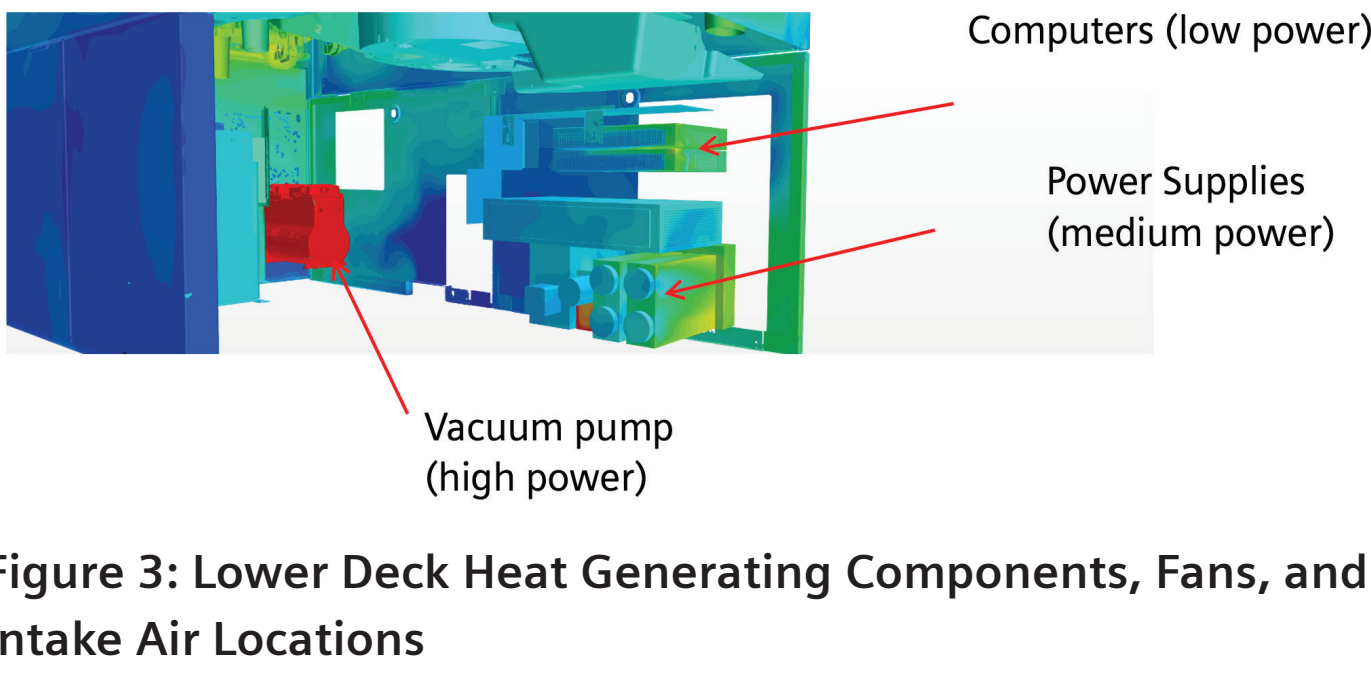


Figure 3: Lower Deck Heat Generating Components, Fans, and Intake Air Locations

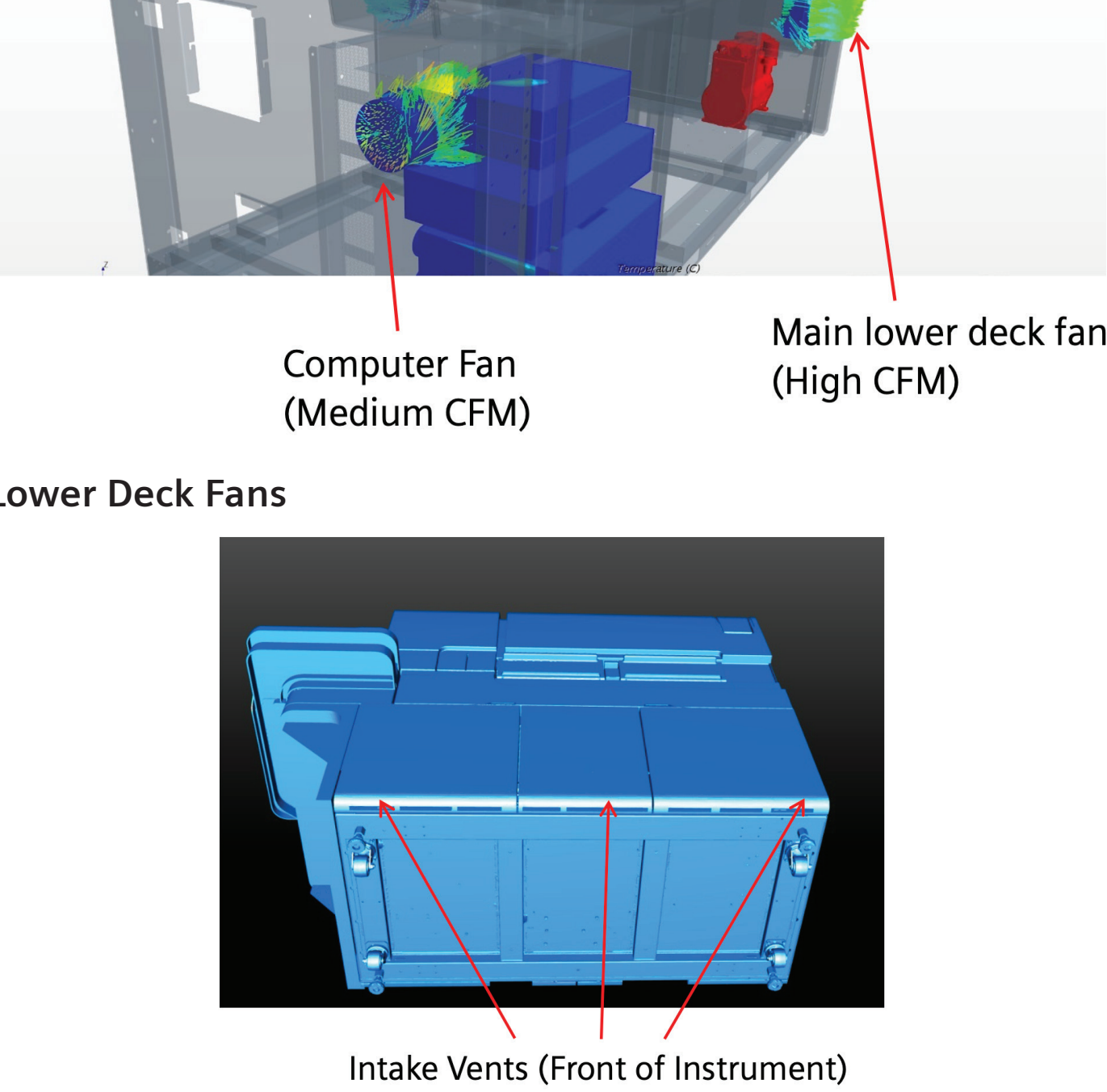


Figure 4: Cool air is drawn in through intakes at the front of the instrument.

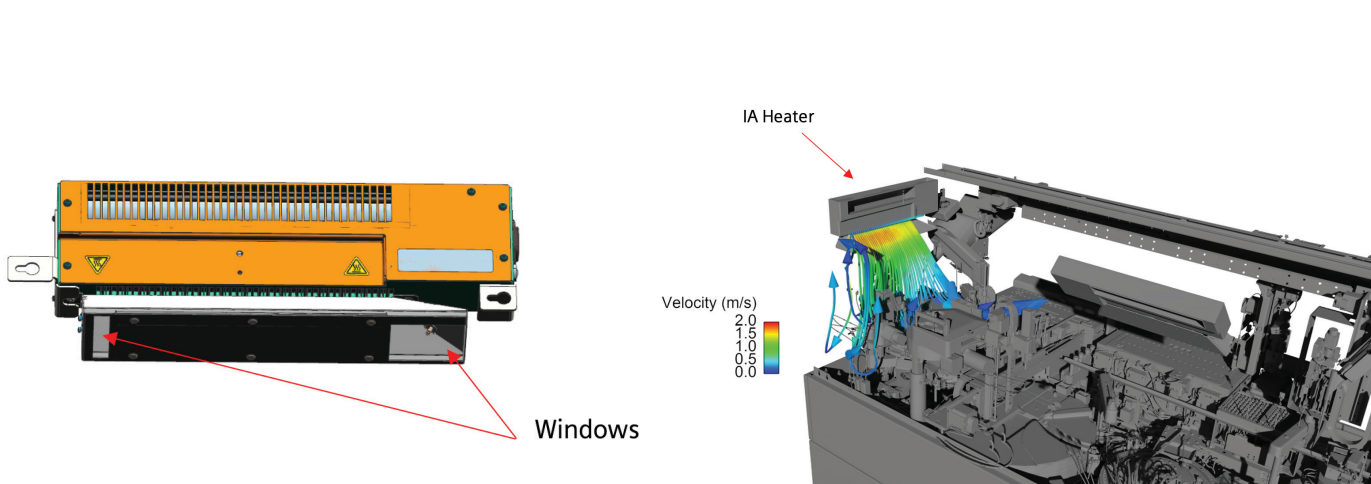


Figure 5: IA's baffle design included two windows and contoured surfaces to achieve optimal airflow distribution over the IA engine, refined through a series of CFD simulations.

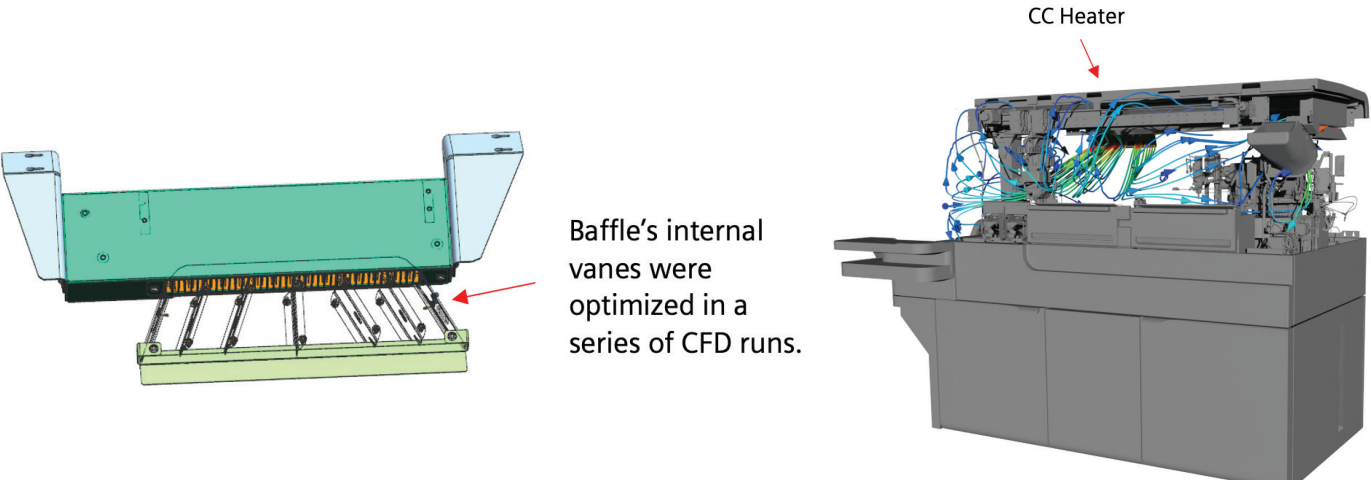


Figure 6: The optimized CC side baffle and heater assembly, along with the resulting streamlines, demonstrate effective airflow distribution beneath the gantry, where the sample probe operates.

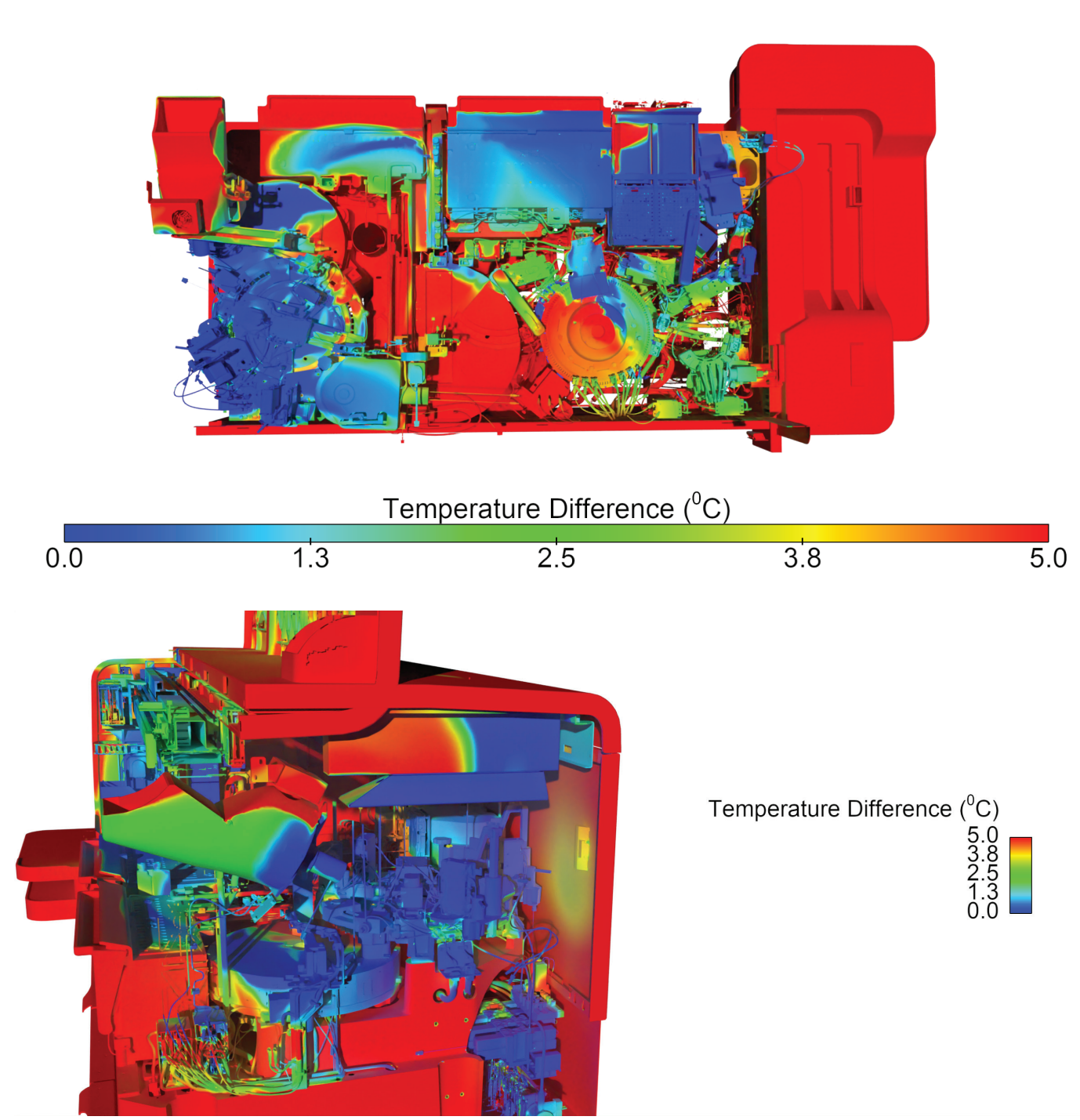


Figure 7: Upper deck temperature difference between 18°C and 30°C ambient conditions. Key areas (contours of blue color) exhibit no temperature variation, which was crucial for minimizing assay bias.

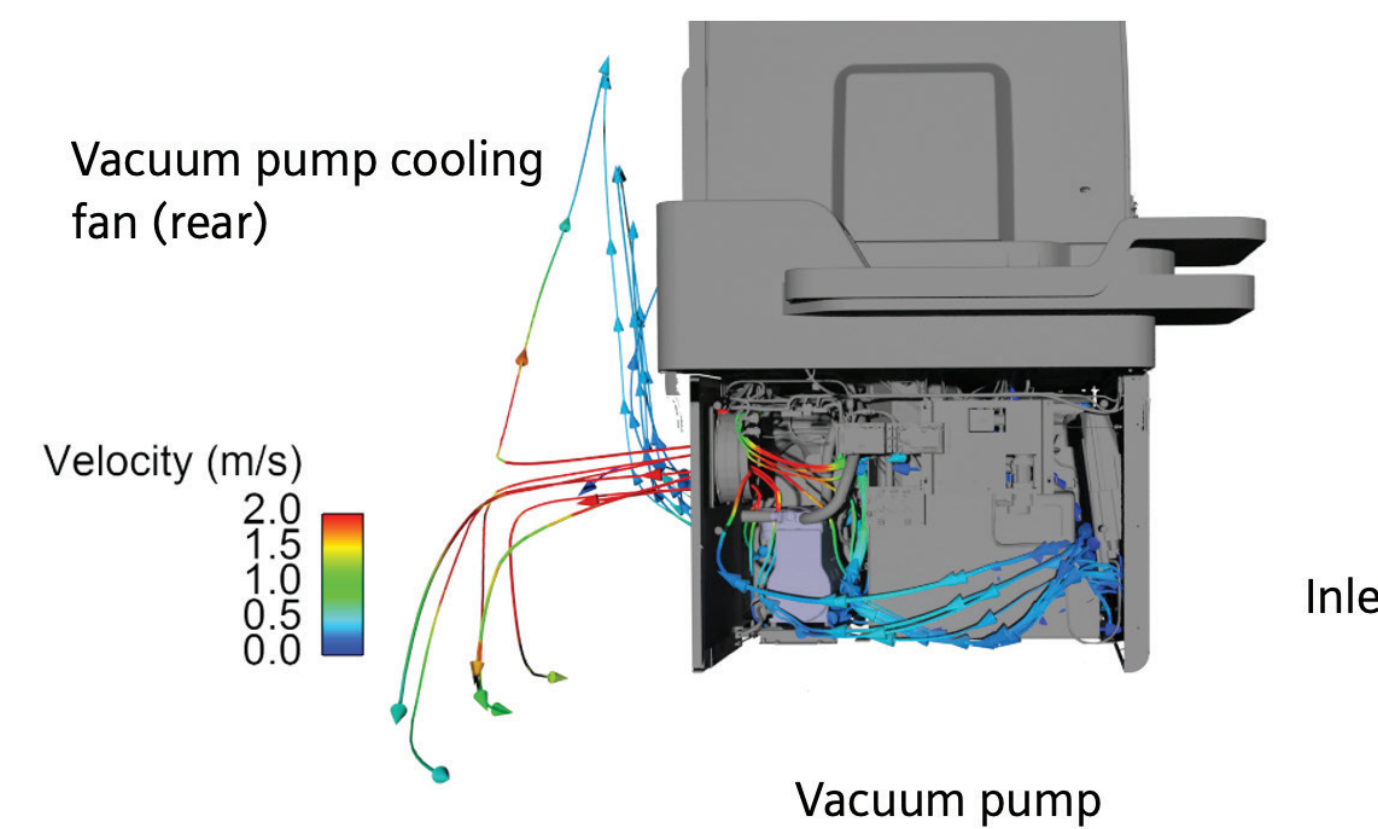


Figure 8: Streamlines originating from the front of the instrument illustrate effective airflow over the vacuum pump, one of the highest heat-generating components.

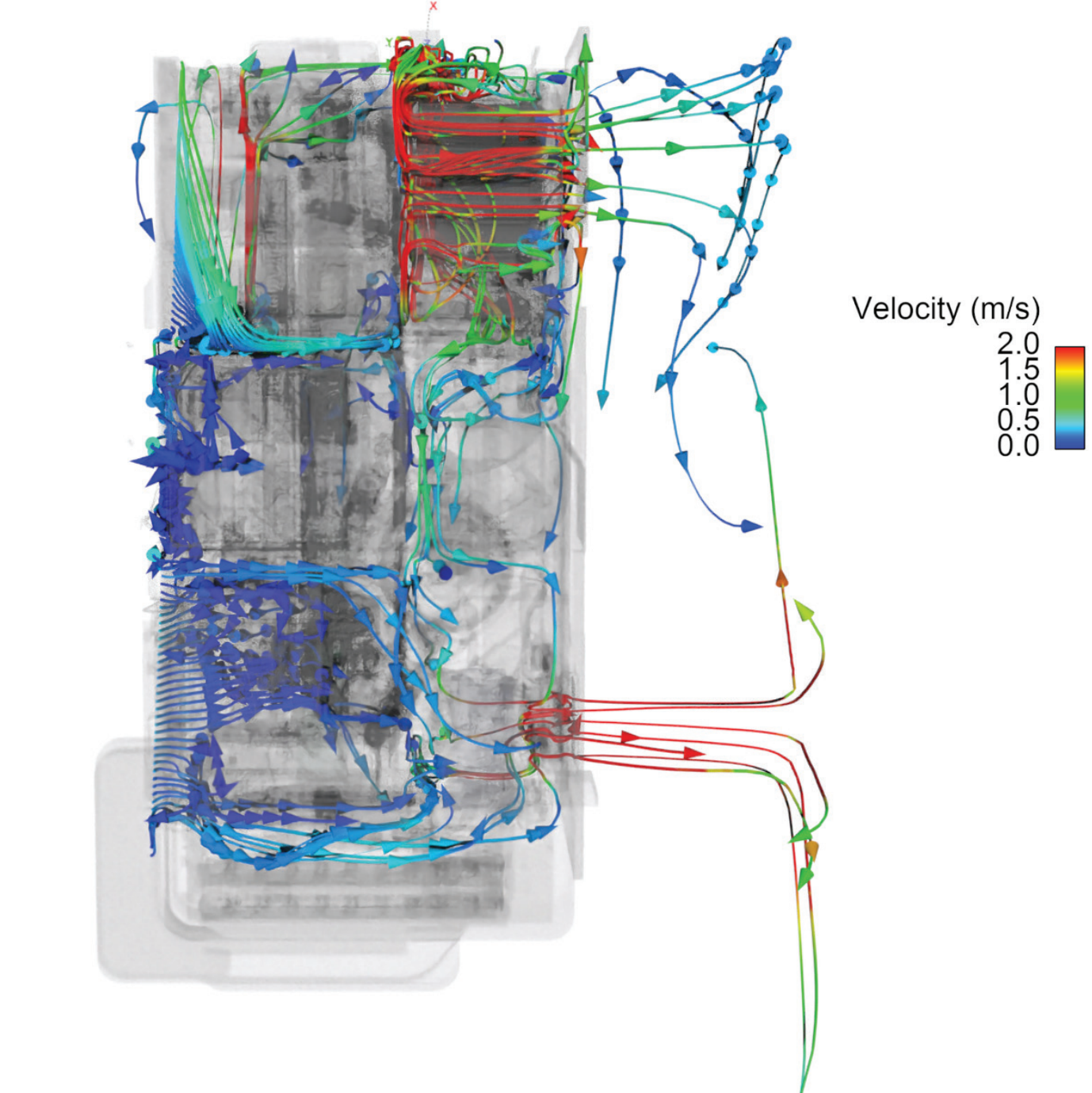


Figure 9: Bottom view into the lower deck, with streamlines illustrating the overall front-to-back cooling airflow managing the most critical power electronics.

Conclusions

The application of modern CFD tools, which accounted for all modes of heat transfer, enabled the rapid virtual design and optimization of the Atellica CI Analyzer complex thermal management system. This approach minimized the need for extensive experimental testing and ensured minimal bias in assay results, regardless of laboratory temperatures.

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