Community Blood Center

New York Blood Center Enterprises

Building A Molecular Lab That Works

Startup to Relocation

Jack Wilson

Regional Director, Immunohematology – Midwest

Our Scope

Local Service, National Strength

NYBCe and its operating divisions serve 75 million people, providing 1M+ products to 400+ hospitals and a comprehensive menu of services to institutions across the U.S.

8 Operating Divisions

61+ Donor Centers

Our Community Blood Centers

- Blood Bank of Delmarva
- Community Blood Center
- Innovative Blood Resources
- Memorial Blood Centers
- Nebraska Community Blood Bank
- New York Blood Center
- New Jersey Blood Services
- Rhode Island Blood Center
- Connecticut Blood Center

Our Business Units

- New York Blood Center Enterprises
  - Lindsley F. Kimball Research Institute
- New York Blood Center Enterprises
  - National Cord Blood Program
- New York Blood Center Enterprises
  - National Center for Blood Group Genomics
- New York Blood Center Enterprises
  - Specialty Pharmacy Services

Comprehensive Cell Solutions

NYBCVENTURES

NYBCe Laboratory Services

Our world-renowned laboratories help medical professionals around the world. From routine screenings and complex antibody investigations to extended phenotypes and detailed molecular analysis of blood groups, we deliver solutions and technical expertise. Our laboratories serve blood centers, hospitals, clinics, university medical centers, and testing laboratories.

Laboratory Services:

- Infectious Disease Testing and Donor Screening
- Immunohematology Reference Lab
- Genomic Testing for Blood
- Molecular Testing for Patient and Donor
- Gene Specific Amplification and Sequencing
- HLA Testing for Blood and Cell Therapy
- Redi-Kit Sample Shipping Transport from Hospitals to our Testing Facilities

Why This Story Matters

How we started…

This year marks 10 years of our genomics laboratory.

- What started as:
- An idea
- A small project team
- An empty space
- 1st year of testing tested appx 1,000 donor and patient samples

Why This Story Matters

Where we are now…

Has grown into:

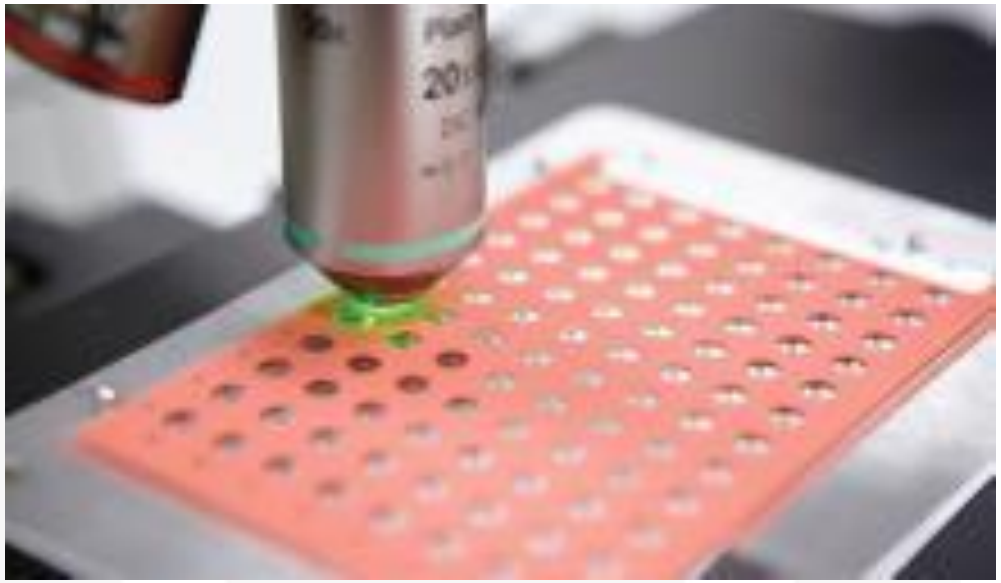
- Steady and consistent growth over the last 10 years
- By 2025, tested **30,000** donor samples and **6,000** patient samples annually
- A **high-throughput national testing laboratory**
- Supporting **300–500 samples per week**
- Supporting **transfusion medicine on local and national level**
- Cutting edge **research on the future of molecular phenotyping**

Today I want to share the story of:

- **How it started, how it grew, and how we recently moved the entire lab.**

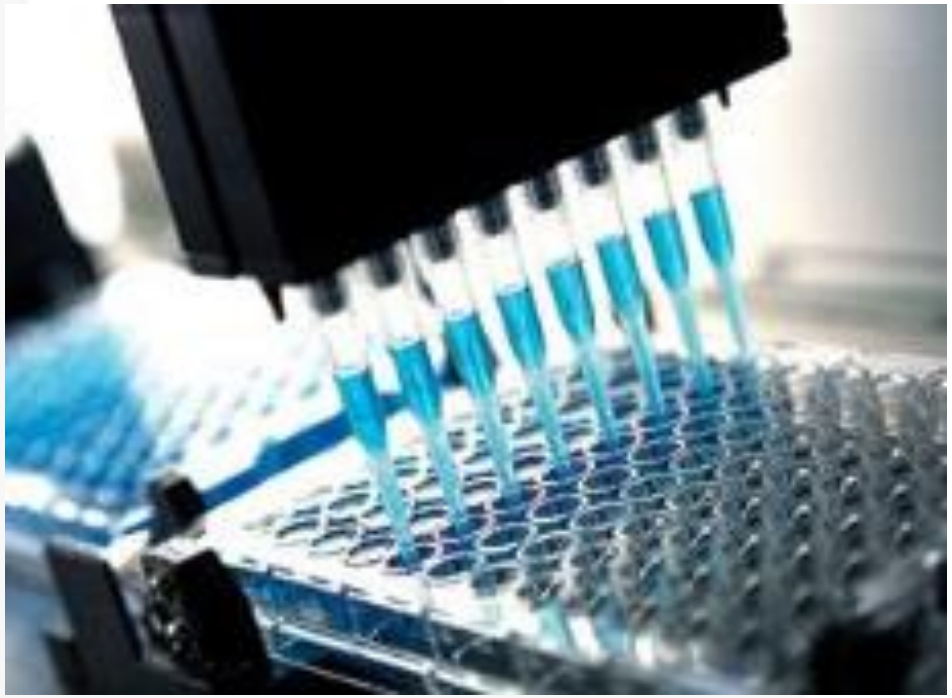
Main Services We Offer

- Complete (extended) blood-typing using next generation genomics (HEA, RHD, RHCE)
- Genomics testing services (patients and donor centers)
- Fetal and neonatal testing, treatment and management options
- Precisematch™ blood products



Three Core Aims

1. To support hospitals by providing extended antigen typing
2. To partner with blood centers to develop highly characterized donor pools
3. To advance research and platform development, with the goal of developing an all-in-one genomic solution for human erythrocyte, platelet, and leukocyte antigens



Where We Are Helping The Community

Serving the KC Metro as well as the Nation

- **70 midwest hospitals served**
- **Over 200,000 donors screened**
  - Built local KC antigen negative donor pool
  - Able to offer better matches for SCD, Warm Auto, alloimmunized patients
- **50,000 patients tested**
  - Better quality serology investigations – replaced microhematetric cell separations
  - Offer personalized units to patients
- **Antibody Registry**
  - HEA results are entered into the registry so the patient is tested once and the community benefits
- Expanded to offering testing throughout USA and worldwide

Antibody Registry

- The Antibody Registry – local CBC customers have access
- Patient Care Comes First!
- Important to local patient care that vital information regarding transfusion is available to transfusion facility
- All patient's with allo antibody identified locally are available on the Antibody Registry
- In 2018, all patient's tested at NCBGG have their antigen typing history available.

DATE OF TEST	ANTIBODIES	ANTIGENS
04.03.2018		E-, c+, C-, e+, V-, VS-
04.03.2018		K-, k+
04.03.2018		Fy(a-), Fy(b+), Jk(a+), Jk(b+), M-, N+, S-, s+, U+
04.03.2018		Do(a+), Do(b+), Co(a+), Co(b-)
04.02.2018	HLA antibody	
02.23.2018	Fy^a	
02.13.2018	C, D	

The Opportunity

How It Started

In Summer 2016, CBC was approached by world renowned Dr. Connie Westhoff, a leader in blood group genomic

- Goal: establish a **high-throughput genomics testing site**
- Focus on **blood group DNA testing and donor genotyping**
- Intended to support **national testing needs**

Who is Dr. Connie Westhoff?

Constance M. Westhoff, SBB, PhD.

Executive Scientific Director, Immunohematology and Genomics

- Internationally recognized investigator expert in **blood group genetics and transfusion medicine**
- Known for her seminal discoveries regarding Rh – what we know of Rh Positive or Negative
- Pioneer in **molecular blood group testing** recognized for establishing high-throughput DNA-based methods
- Advanced **DNA-based donor typing** fundamentally changed and improved standard practice in blood transfusion.

Her vision:

- Expand **molecular testing access**
- Improve **matching for complex patients**
- Support **research and innovation**

The Challenge

Build it in 6 Months

We had 6 months to…

1. Secure a location
2. Buy equipment – arrange for delivery and installs
3. Secure contracts with suppliers
4. Draft / Execute Validation Plans
   - Equipment
   - Assays
   - Process
5. Notify customers
6. Hire and train staff
7. Begin accreditation process as an AABB and NY State accredited lab

The Project Team

- **Building the Right Team**
- This required collaboration across multiple departments.
- Project team included:
- Project manager
- IT specialists
- Building operations
- Lab leadership
- Dr. Connie Westhoff
- Senior technical leadership
- Myself as lab manager

My responsibilities included:

- Hiring staff
- Designing workflow
- Writing procedures
- Equipment validation
- Staff training
- Operational launch

The Design

Designing the Lab

Genomics workflows differ from traditional serology.

- Key considerations:
- **Contamination control**
- **Unidirectional workflow**
- Pre-PCR vs Post-PCR separation
- Specimen handling and tracking
- High-throughput sample processing
- Data analysis pipelines

Designing the space meant planning for:

- Efficiency
- Scalability
- Quality control

Designing the Space

Planning for Efficiency

- Important design factors:
- Separation of extraction, amplification, and analysis areas
- Adequate electrical and data infrastructure
- Environmental controls
- Sample storage
- Freezer capacity
- Equipment footprint
- One key lesson:

Lab design must follow workflow — not the other way around

Leason Learned – Lab Space

Build in Flexibility – Room to Grow

- Had to make a significant change just prior to equipment arrival
  - Switched the workflow direction to allow for more space in Post PCR
  - Acquired a PK7300 late in the planning stages we had to accommodate
  - Needed every inch of it + more within a few short years

Trash pickup rotation to reduce contamination

- Consider the janitorial staff and limited access to trash pickup / mopping
- Designated pickup areas. Reserve cleaning to designated personnel

Leason Learned – Lab Space

Environmental Monitoring

- HVAC system – ensure it is capable of maintaining proper humidity / temp controls

Electrical and Network Needs

- Required several line drops and plug-in conversions from 120v -> 220v

Elevators – measure them before buying equipment

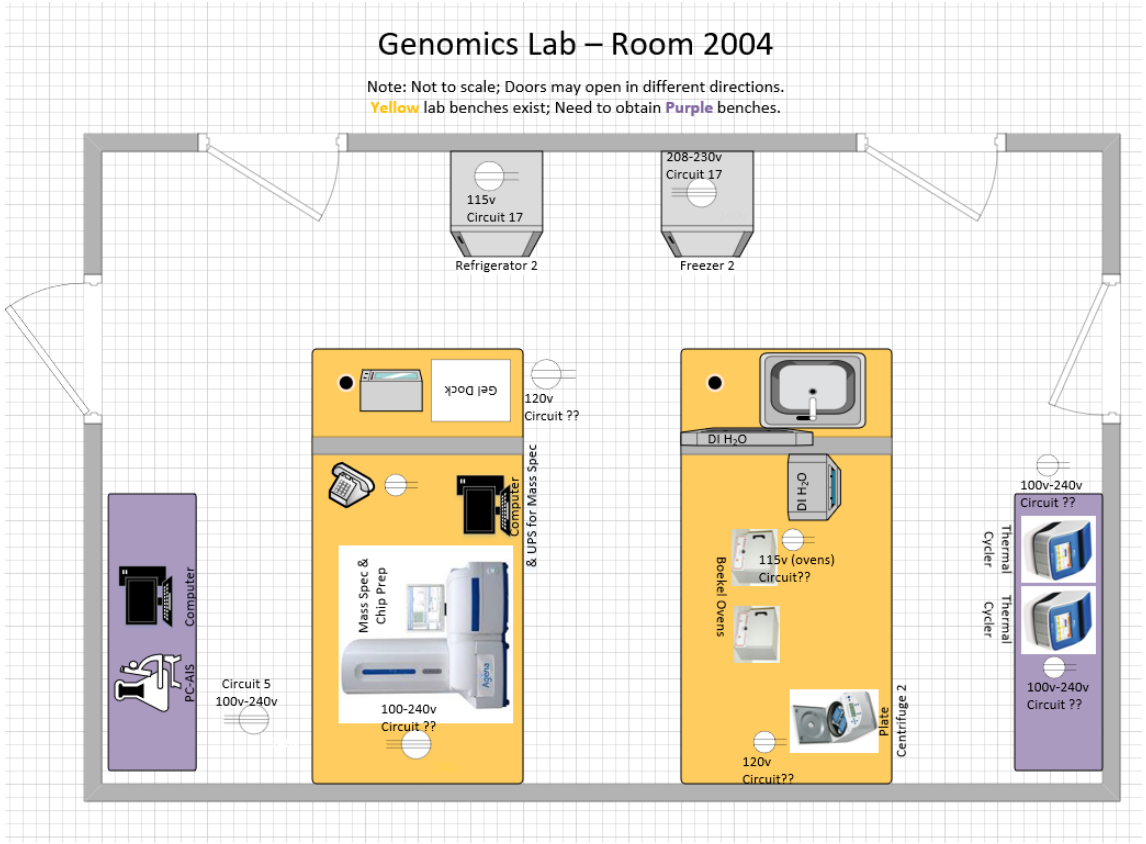
- Had to return a DNA chest freezer because it wouldn't fit in the elevator

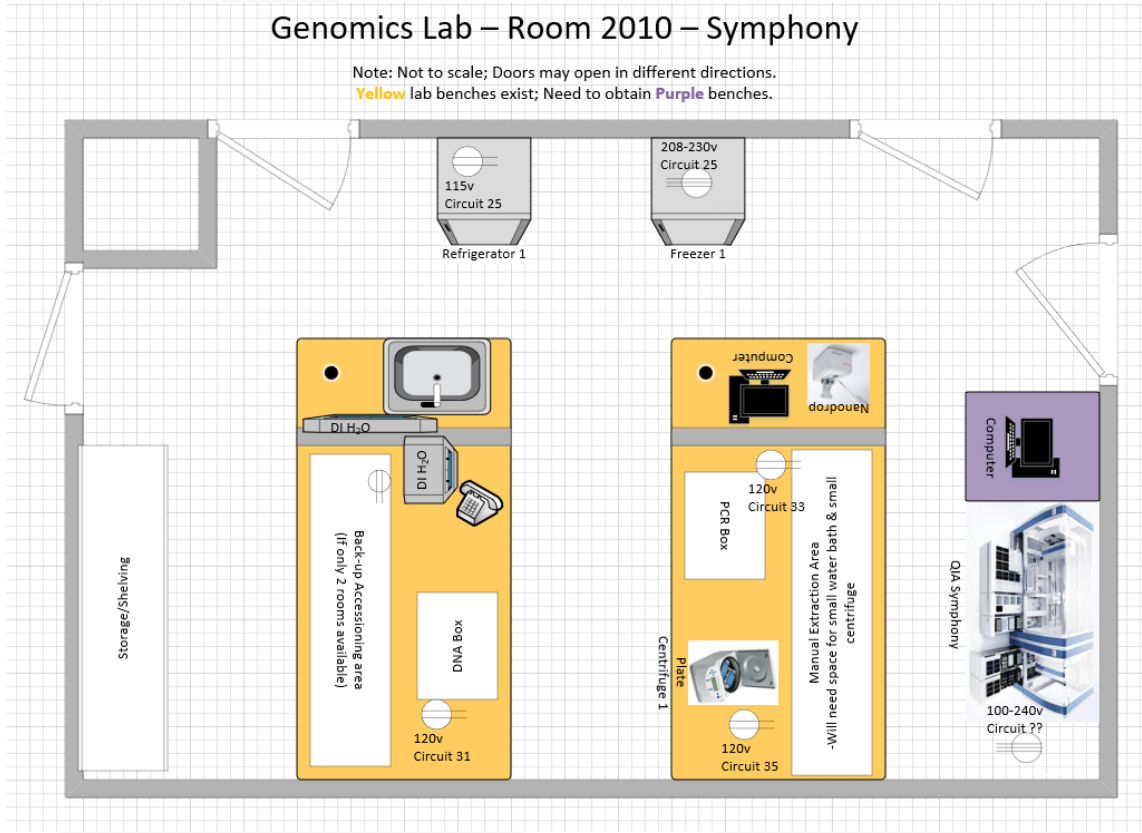
Don't put the lab on the 3rd floor!

- Moving anything in/out was a pain

Lessons Learned – Lab Space

Microsoft Vizio Is Your Friend for Designing the Space





The Equipment

Equipment and Validations

Getting the Lab Operational

Major equipment included:

- DNA extractors
- Thermocyclers
- Assay specific equipment
- Freezers and storage systems

Before launch we had to complete:

- Equipment qualification
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Plus:

- Method validations
- Procedure development
- Staff competency

Leason Learned - Equipment and Validations

Triple Check Before Buying Equipment

- Measure the elevators and be sure the freezers match the storage needs of the reagents (don't buy a -80C unless you need it)
- Plan for long term storage and back-up storage – contingency plans; make them before you need them

Review all Equipment Maintenance

- Don't be surprised by required PMs you didn't consider.
- We found a last minute addition to thermocycler maintenance we missed on the first implementation
- Ensure proper documentation of all maintenance is recorded and kept
  - Created a single bulk form to capture all monthly maintenance

Leason Learned – Process and SOP design

Don’t Reinvent the Wheel

- Use templates or past validation plans as much as possible – creating from scratch = wasted time (same goes for SOPs)
- I pulled from IRL process, old Donor Testing lab and NYBC genomics lab for most procedures

Identify Critical Steps Early

- Build in protections – 2nd check checks prior to moving forward
- Accessioning – DNA addition on – Reporting
- Encourage staff to identify them (protect against your own blind spots)

Staffing and Training

Building the Right Team

Hiring Adaptable Staff With Strong Problem-Solving Skills

Staffing approach

- Identify individuals comfortable with **molecular workflows**
- Build a team capable of supporting **multi-tasking** and **high-throughput testing**

Training approach

- Training on **DNA extraction and downstream molecular workflows**
- Instrument operation and troubleshooting
- Data analysis, interpretation and reporting
- Quality systems and contamination prevention

Competency and quality

- Structured training plans and competency assessments
- Procedure development alongside training

Lessons Learned - Staffing and Training

Developing Job Descriptions

- Ensure AABB and regulation requirements are met
- Roles align with CLIA roles and delegations when needed (lab director)

Interview:

- Develop interview guide for the roles
- Allow time for all needed interviewers to weigh in
- Set target hire dates first to allow time for training prior to go-live

Hire for long term – plan for short term

- Cross train in the short term when needed
- Don’t settle – wait for that high quality candidate

Lessons Learned - Staffing and Training

Training:

- Develop training checklists – guides
- Setup fake samples for process – make samples for accessioning / reporting
- Build training into the PQ where it would help
- Schedule vender training and supplement with institutional specific training

Accreditation and Regulatory Considerations

Accreditation and Regulatory Considerations

Goal: Become AABB and NY State Accredited Within 1st Year

When drafting policy/process we considered:

- AABB Standards for Molecular Labs
- New York State Lab and Immunohematology Requirements

Quality management system integration

- Documentation and validation standards
- Staff training and competency
- Ultimately, we achieved:
- **AABB and New York State accreditation for high-throughput testing**

Association for the Advancement of Blood & Biotherapies

Lessons Learned – Accreditation

Expect Regorous Inspections

- Initial inspections are extremely detailed and time.
- Don’t let the inspector touch a sample w/o gloves…. Long story
- Ensure all experts are available for the inspection – not a typical inspection (all hands on deck)

Quality Manual

- Ensure the lab has a dedicated quality manual or is listed in the existing manual
- Ensure CLIA lab role delegations are documented

Lessons Learned – Accreditation

Dedicated Individual Responsible for Submittions

- No realistic for lab manager to lead this – had QM Director complete the paperwork
- A lot of communication and requirements from AABB/CLIA/NY State
- Enrollment in available PT programs

Consider Standards When Drafting Process/SOP

- Place the standard directly in a policy document and then have the process/ SOP match the policy
- Consider standards up-front and when designing processes (request forms, final reports, review requirements, operational controls, job descriptions, minimum requirements for resource inventory)

10 Years of Growth

Nearly A Decade Growth

Over the past decade the lab has expanded significantly

Today we perform:

- **300–500 samples per week**

Current capabilities include:

- Two DNA extractors
- Multiple thermocyclers
- High-throughput work area and reduced bottlenecks
- Research studies to drive the future of blood group genotyping

We are now:

- **One of the only AABB and New York State accredited high-throughput genomics labs.**

A New Challenge

Outgrowing Our Space

In 2024 we had to pack-up and move out

After 8 years in our original location:

- We were informed that our **lease would not be renewed**.
- The space had originally supported **startup labs**, and we were no longer considered one.
- So we had to find a **new home for the lab.**

The 2024 Move

- We ultimately relocated the lab to **Waldo in Kansas City, Missouri.**

Now Challenge:

How do you move a **high-throughput molecular lab** without interrupting operations?

Our solution:

- **Move in phases.**

Goal: Moving Without Downtime

Our strategy was to maintain operations while building the new lab.

Steps we took:

- Move **half of the equipment** to the new facility
- Validate instruments at the new location
- Continue testing operations at the original site
- Transition testing once the new lab was operational

Result:

- **Next to zero operational downtime**

Lessons Learned - Completing the Move

Patience Paid Off

Did not go with the 1st few options - took several months for a space to open up. **And it was worth the wait!**

With Change Comes Opportunity

We successfully worked with vendors to get upgraded equipment. They set it up at the new space prior to the move. Once fully moved we gave our old equipment back.

Move and Validate in Phases

Phase 1: Moved redundant equipment to the new space + new equipment.

Phase 2: Moved testing to new lab.

Phase 3: Shut down old lab - moved remaining equipment to new lab and validated it for use.

Customize the Space For Your Needs

Placed walls, installed doorways and ran all network cables and powerlines prior to moving in. Connected as many power outlet to generator backup power.

Overall Thought

Project Manager to ensure everyone does their part. The move ended up being **one of the smoothest projects I've ever been involved in.**

New Lab Tour

This short video gives a quick tour of our new genomics laboratory in Kansas City.

Final Thoughts

Final Reflection After Nearly a Decade

Ten years ago:

- No lab
- No equipment
- No staff

Today:

- A national genomics testing lab for patients and donors
- Supporting patients and donor centers nation wide
- Active participation and leadership in clinical testing and research developing an all-in-one next gene platform
- Operating in a brand new state of the art facility
- **It has been an incredible journey.**

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