Implementation of Molecular Testing – The Carter BloodCare Experience

Presented by:

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Director - Reference & Transfusion Laboratory Services

R&T Services Departments

- **Reference & Transfusion Laboratories:**
  - **AABB Accredited Laboratories - Bedford, TX:**
    - **Immunohematology Reference Laboratory (IRL)**
    - **Centralized Transfusion Services**
    - **Molecular Testing (MT)**
      - **2nd AABB accredited MT laboratory in the nation**
  - **AABB Accredited Laboratory – Dallas, TX**
    - **Transfusion Services – Medical City Dallas**
      - **Level 2 pediatric & Level 4 adult trauma**
  - **AABB Accredited Laboratories – Fort Worth, TX**
    - **Transfusion Services - John Peter Smith**
      - **Level 1 adult trauma**

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R&T Services Departments

- **R&T Services Laboratories (3 Locations):**
  - **Staffing – 82** (including 12 SBBs, 2 FCS, & 1 PSC**)**
  - **2017 IRL Workload:**
    - 388,117 Tests Performed
      - 250, 827 IRL (~ 2,200 requests per month)
      - 595 Antibody Identification Workups per month
        - 203 Modified Workups (~ 17 per month)
    - 4, 814 Antigen Negative Units Requests (~ 401 per month)
      - Shipped 32,227 Antigen Negative Units
      - 831 Rare Units Shipped
        - 50 Rare Units Exported (23 Exported Out of State)
    - 1,515 Molecular Testing (Donor & Patients)
      - ~10 patients per week since implementation of Modified Wkup
      - ~ 3-5 patients per week since new Drug for CD38

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Why Bring In Molecular Testing?

- **CHANGING INDUSTRY & CHALLENGES:**
  - **Increasing Workloads**
  - **Increasingly Complex Patient Workups**
  - **Increasing Needs for Antigen Negative Units (ANUs)**
  - **Customer Satisfaction, Retention & Growth**
    - Requesting Cost Reductions/Containments & Decrease TATs
  - **Meeting AABB Accreditation IRL Requirements**
  - **Internal Cost Containment Initiatives**
    - Mass Screening of Multiple Antigens w/Limited Staffing
    - Increase Antigen Typed Donor Database
    - Streamline Patient Workups Workflows
  - **Increase Revenue with Diversified Services**
    - Reagent Manufacturer Vendors
    - Export Rare Antigen Negative Units

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Why Bring In Molecular Testing?

- **Limitation of Serology**
  - ❖ **Subjective Interpretations By Technologist**
  - ❖ **Labor Intensive Procedures**
  - ❖ **Escalating Costs of Licensed Antisera**
  - ❖ **No Commercial Licensed Antisera Available**
  - ❖ **Known to Mistype Some Variant & Partial Antigens**
  - ❖ **Limited Volume/Specificities of IRL Rare Inventories**
  - ❖ **Inability to Accurately Type Some Patients**
    - ➢ Positive DAT
    - ➢ Recently Transfused
    - ➢ Decreased Neocyte Production
  - ❖ **Collection of Multiple Blood Samples from Anemic Patients for ABID Workups**

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Benefits of Molecular Genotyping

- **Mass Scale Genotype Screening of Donors for Both Common & Rare Antigens**
  - ❖ **Large number of samples tested for a vast number of antigens in a short time with limited staffing required**
  - ❖ **Larger supply of a readily available ANU inventory**
  - ❖ **Increased antigen typed donor database**
    - ➢ Decreased need for importing rare ANUs
    - ➢ Phenotype “in-house” reagent red cells
    - ➢ Larger quantity of cells available for adsorptions
    - ➢ Determine zygosity (dosage) on donor reagent RBCs
  - ❖ **Confirm certain rare types (i.e. U negative, hr^B negative, Dombrock system, etc…)**

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Benefits of Molecular Genotyping

- **Maintaining IRL AABB Accreditation Requirements**
  - **IRL AABB Accreditation Standard 5.2:**
    - Participation in the American Rare Donor Program (ARDP):
      - Screening donors for high incidence antigens (Min. 1,000)
      - Units shipped (Min. 15)
    - Family Study (Min. 1)
    - Shared Rare Antisera/Cells with another IRL
  - **IRL AABB Accreditation Standard 5.2.1**:
    - Register at least 10 donors in ARDP
  - **IRL AABB Accreditation Standard 2.2:**
    - Maintain appropriate inventory of antisera, reagent red cells and reagents for testing as outlined in the tables (2.2A & 2.2B).
    - Confirmation of reagent red cell phenotype, shall be performed by molecular testing for hr^B-, hr^S-, V-, VS-, U-, Do(a-), Do(b-), Hy- and/or Jo(a-).
    - Molecular as sole method of determination for: Hy-, Jo(a-), Js(a-), and/or Lu(a-).

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Benefits of Molecular Genotyping

- **Use of Molecular Genotyping for Patients**
  - **Select Patient Populations for Provision of Genotype Matched Donor Units**
    - Hemoglobinopathies (i.e. Sickle Cell Disease, Thalassemia, etc.)
    - Aplastic Anemia
    - Anemia of Chronic Disease
    - Oncology (Myeloid Leukemia)
    - Warm Autoimmune Hemolytic Anemia
  - **Problem Phenotyping Certain Patients**
    - Recently Transfused
    - Positive Direct Antiglobulin Test (DAT)
    - Rare Blood Group Phenotype
    - Recent Bone Marrow / Stem Cell Transplants
    - Medication Complications (i.e. Multiple Myeloma)

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Benefits of Molecular Genotyping

- **Complex Patient Antibody Identification Workups**
  - **Provides predicted common & rare blood group phenotypes for problem patients**
    - Patients Unable to Get a Phenotype w/Serology
    - Multiple Antibodies
    - High Prevalence Antibodies
    - Detection & Confirmation of Other Rare Antigen Types (i.e. Dombrock, hr^B, Lutheran, etc…)
  - **Identifies nucleotide substitutions, deletions, insertions & gene conversions that determine the expression of antigens on the RBCs**
    - Rh Variances & Other Variances
    - Partial D
    - GATA Mutation

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Benefits of Molecular Genotyping

- **Streamline Patient Antibody Identification Workups**
  - **Reflex Molecular Genotyping & Modified Workups**
    - **Candidates:**
      - Select Patient Populations
      - Problem Patients w/Complicated Workups
      - Physician Requested
    - **Initial Patient Workup:**
      - Antibody Identification – omit the phenotyping and reflex for molecular genotyping
        - If unable to wait for genotyping results and units are needed immediately perform differential adsorption and issue units per normal R&T protocols.
    - **Subsequent Patient Workups:**
      - Type, Antibody Screen & DAT
        - Provide phenotyped donor units that matches the patients genotype (as available). If not available will proceed with full antibody identification workup per SOP.

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Client Hospital Cost Savings

- **Pilot Cost Analysis – Modified Workups (Tracked/1 year)**
  - Patient w/WAA, Anti-E, Anti-Fy^{a} & Anti-Jk^{b}
    - Initial Workup: ***Cost $1200 TAT: 9 hours***
    - Place on Modified Workup Protocol
      - Transfused with 35 units
      - Average TAT: **1 - 3 hours**
      - Client Savings**: $19,000**
  - Patient w/WAA, Anti-E & Anti-K
    - Initial Workup: ***Cost $1100 TAT: 12 hours***
    - Place on Modified Workup Protocol
      - Transfused with 33 units
      - Average TAT: **1 - 2 hours**
      - Client Savings: **$15,000**
- Current WAA Antibody Workup Protocol
  - Average Cost: ***$765 - $1,700 TAT: 8 – 12 hours***
    - Initial Workup: Savings Cost **$200** w/Genotyping
    - Initial Workup Time Savings: **3.5 hours**

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Client Hospital Cost Savings

- **Pilot Modified Workup Cost Analysis Summary**
  - Molecular Genotyping, Performing Modified Workups & Giving Phenotypically Matched RBCs:
    - **Increased Customer Satisfaction & Retention**:
      - Complex Workup Cost Savings for Clients
      - Decreases Preliminary Workup Results Turnaround Times
      - Gets Safer Blood Products to the Patient Faster
      - Increased Patient Safety & Care
      - Decreased Chance of Patient Making Alloantibodies
    - **IRL Works Smarter With Increased Workload, Limited Staffing & Provides a Higher Quality of Results To Clients.**
      - Budget Constraints & Potential to Recoup Costs w/ANUs
      - Provide Accurate Phenotyping Results for Problem Patients
      - Takes Less Sample from Anemic Patient
      - Will not potentially miss weak alloantibodies diluted out during adsorption
      - Provide Molecular Matched Units (i.e. r's , Do(a), etc.)
      - Helps keeps the technologists from going crazy

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R&T Tyler - Molecular Genotyping

- **Installation of Molecular Genotyping Technology**
  - **2008 – 2010 BioArray Solutions *HEA Beadchip™***
    - **Started with Donor Screening & Limited Patient Testing (96/run)**
      - **2008 Molecular Testing Criteria:**
        - First 94 donors without any antigen typing history per week
        - Screening 4,800 Donors
      - **2009 – 2011 Molecular Testing Criteria:**
        - All O donors without any antigen typing history & with at least 4 or more donations
  - **2010 Progenika ID-CORE™**
    - **Screening Donors & Patient Testing (48/run)**
      - Moved because of pricing, rare antigens offered with ID-Core & problems with testing southern AA donors (particularly problems with making the C calls)
  - **2011 Genprobe Genotyping Platform (Luminex based)**

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R&T Tyler - Molecular Genotyping

- **2011 – 2013 Progenika ID-CORE Plus™**
  - **2012 – 2013 Molecular Testing Criteria:**
    - AA donors without any antigen typing history (or limited) with at least 4 or more donations
    - Backfill with any HI donors as needed
- **2013 – 2014 BioArray Solutions *HEA Beadchip™***
  - **2013 Progenika ID-CORE XT™**
    - Dual Platforms:
      - Progenika ID-Core XT™ – Patients & AA Donors
      - BioArray *HEA Beadchip™* – CA, PI & HI Donors
        - Correlation and troubleshooting with dual platforms
  - **2014 Discontinued BioArray Solutions *HEA Beadchip™***
  - **2014 Molecular Testing Criteria:**
    - AA donors without any antigen typing history (or limited) with at least 3 or more donations
    - Backfill with any HI or PI donors, as needed
  - **2015 Molecular Testing Criteria:**
    - Added PI donors and drop to 2 donations

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R&T Tyler - Molecular Genotyping

❖ 2014 – Present Progenika ID-CORE XT™

- **Budgetary constraints unable to maintain MT duel platforms**
  - Increased pricing for FDA Licensed BioArray Solutions & discontinuation of RUO platform. Removed BioArray from MT lab.
- **Decided to Maintain the Progenika ID-CORE XT™ Platform:**
  - Reasonable pricing options
  - Simplified testing for a better workflow (faster TATs)
  - Increased rare antigen detection:
    - Cw, V, VS, hr^B, hr^S, Mi^a, Diego, Colton, Lutheran, Cartwright, Dombrock & several other gene mutations reported
    - Alleles assayed pickup up variances specific to the southern AA populations which was very important to us
      - With the increase in r's with SS patients we needed to be able to differentiate between hr^B & hr^S
  - The way we use RUO results:
    - Confirm all unit antigens with commercial licensed antisera
    - Clients can still use the CPT codes w/RUO
    - No added benefit of FDA licensed genotyping.

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Molecular Genotyping Benefits

- **Molecular Genotyping Summary:**
  - **Increased Antigen Typed Donor Database**
    - Decreased Importing & Increased Exporting of Rare ANUs
    - Increased Readily Available ANU Inventory (Including Liquid & Frozen Rare ANUs)
  - **Increased Customer Satisfaction**
    - Decreased Client Costs & Decreased TATs
    - Provided Increase In Patient Safety & Patient Care
    - Meeting Client Requests for HANU, ANU & Rare ANUs
  - **Working Smarter w/Complex Workups, Workloads & Staffing Levels While Remaining Within Budget**
  - **Higher Quality of Patient Testing & Results**

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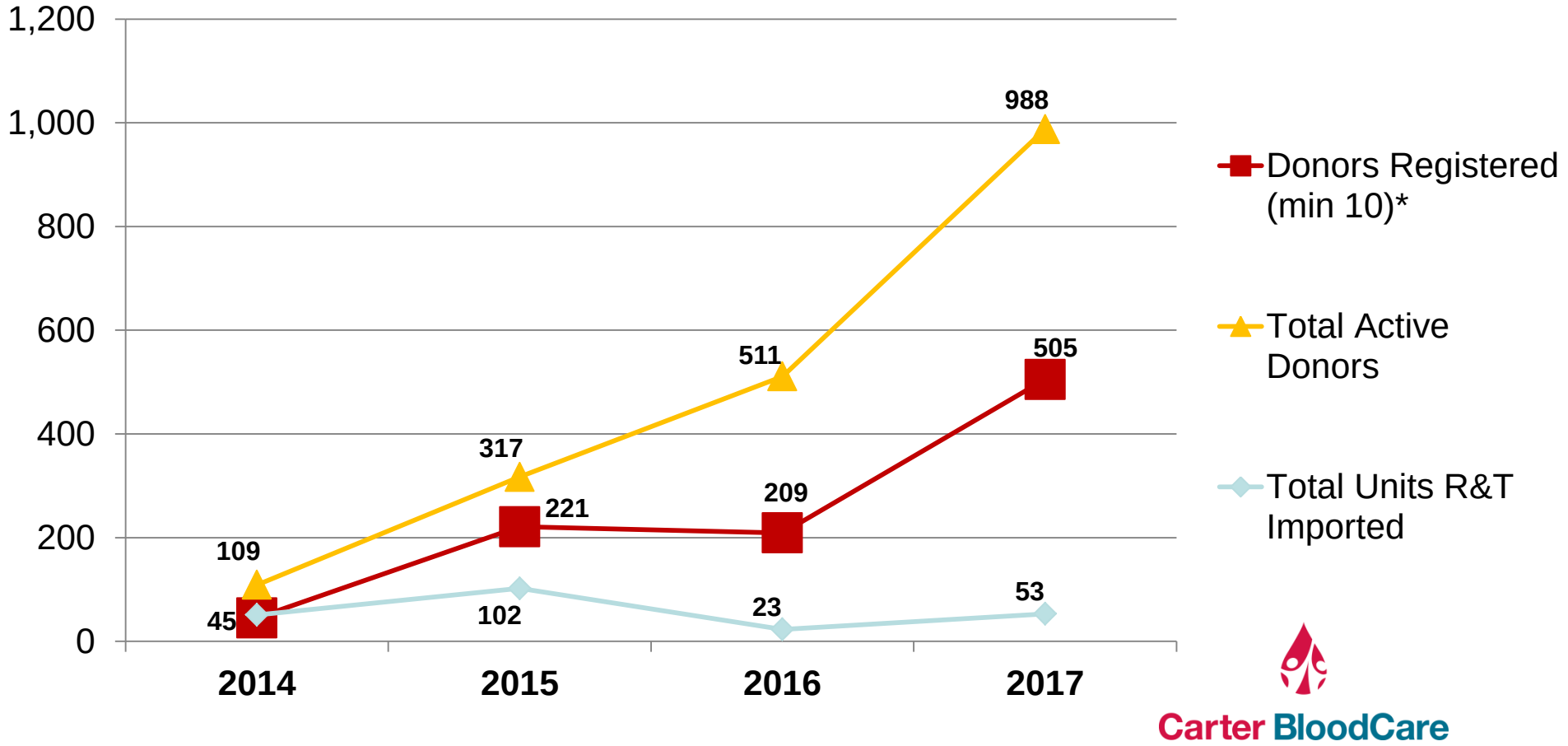
Molecular Genotyping Benefits

- **Meeting All IRL AABB Accreditation Requirements**
  - Maintaining IRL Rare Antisera & Rare Cell Inventories
  - Meeting & Exceeding ARDP Requirements



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QUESTIONS?

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