Validation of Umbilical Cord Blood Sampling to Reduce Phlebotomy Losses in Newborns at Risk for IVH

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Background: Extremely low birth weight infants have a total blood volume of ~ 85 mL/kg. For infant’s weighing 0.5 – 1.0 kg, this equates to an estimated total blood volume of 42 - 85 mL. Testing upon admission to the NICU typically includes a blood culture, type and screen, CBC with differential, blood gas and a glucose; these phlebotomy losses can add up to 3 - 5 mLs of blood, which can be a loss of up to 10% of an extremely low birth weight (ELBW) newborn’s total blood volume. This volume change from phlebotomy losses in the immediate neonatal period has the potential ability to affect hemodynamic stability, which could in turn affect cerebral blood flow possibly contributing to risk for ventricular hemorrhage (IVH). Processes that decrease these neonatal phlebotomy losses might lead to improved postnatal hemodynamic stability.

Aim: To determine procedural feasibility of drawing blood from the umbilical cord/placenta and to determine if those laboratory values accurately correlate with neonatal blood samples. The target set for implementation was September 2015.

Setting: The University of Minnesota Masonic Children’s Hospital, 62 bed, level IV NICU. This academic teaching hospital serves as both a referral center (providing air and ground transportation) and collaboration with high-risk maternal fetal medicine providing care to complex surgical patients and all preterm infants. There are about 750 annual admissions, with approximately 240 transports and about 120 ELBW infants.

Mechanisms: Hemodynamic instability in critically ill newborns can impact cerebral blood flow. Factors that affect hemodynamic instability such as significant phlebotomy losses in the immediate newborn periods in newborns at risk for IVH should be minimized. These postnatal phlebotomy losses occur because of the present practice of drawing all blood samples from the infant including but not limited to blood culture, type and screen, CBC and differential and genetic testing. While there is communication between the NICU and OB teams regarding the clinical situation leading to the presence of the NICU team at the delivery, this communication has been focused on the baby’s anticipated clinical care in the delivery room. Prior to this project, there had not been any attempt at collaboration in this effort to reduce postnatal phlebotomy losses. If it is demonstrated that blood drawn from umbilical cord/placenta correlates...
with blood drawn from the newborn infant by establishing a collaborative process involving neonatology, obstetrics and lab medicine, postnatal phlebotomy losses can be decreased, possibly enhancing hemodynamic instability and decreasing risk for IVH in at risk newborns.

**Drivers of Change:** Multidisciplinary staff education and updates regarding the goal and intended outcomes to increase staff awareness and support of the project. This included frequent updating of staff regarding progress, addressing staff concerns and notifying staff when goals were reached.

### Umbilical Cord Blood Driver Diagram

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Primary Drivers</th>
<th>Secondary Drivers</th>
<th>Process Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>To determine procedural feasibility of drawing blood from UCB/placenta and if those lab values accurately correlate with infant samples. Project aim is driven by the theory that this process will reduce the volume of blood drawn from the infant thereby improving hemodynamic stability which can lead to improved cerebral blood flow and possible reduction of IVH.</td>
<td>Logistical Procedure for drawing UCB</td>
<td>Correlation of UCB values with infant’s values</td>
<td>Staff training</td>
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<td>Work flow adjustments</td>
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<td>Teamwork</td>
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<td>Communication with OB, NICU, and lab for placental custody</td>
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<td>Data analysis</td>
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<td>Logging/tracking data</td>
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<td></td>
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<td></td>
<td>Senior leadership</td>
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<tr>
<td></td>
<td>Training procedure</td>
<td>Staff updates and encouragement</td>
<td>Meetings to review process</td>
</tr>
</tbody>
</table>

**Methods:** A multidisciplinary team was established including personnel from the Lab Medicine and Pathology, Obstetrics, Neonatology, Pediatric Infectious Disease and Blood Bank Medicine. An initial goal of 20 paired samples for testing was set with plans to reassess results frequently. Contact was made with another center (Intermountain Health) that had published data on this process to glean lessons learned from their trial. Particular attention was made to the process for blood culture collection given the data in the literature for issues with positive blood cultures from umbilical cord samples with negative cultures from correlating post-natal samples. Additionally, a correlation of lab results internally is required to establish this process locally.

A detailed procedure was developed with input from OB, NICU and lab medicine for how samples were to be obtained, labeled and processed for analysis. A supply cart was designed for umbilical cord/placenta blood sampling, and one NICU team member was dedicated to obtaining the samples. Staff from OB, NICU and lab were educated
as to the plans for this project, and trained as to accurate drawing procedure for successful sampling. This final procedure follows at the end of this abstract.

Frequent meetings of the multidisciplinary team, and meetings with NICU nurses/NNPs were held to obtain feedback and address staff concerns and to troubleshoot roadblocks. Samples were attempted to be collected over a 4 month period from all the umbilical cord/placenta for all newborns being admitted to the NICU, and these samples were then analyzed for correlation with the paired postnatal sample from the newborn.

The core neonatology team (Julianne Cramer, NNP and Thomas George, MD) presented this planned project to the Department of Pathology. A multidisciplinary team with representation from lab medicine and pathology, labor and delivery and NICU was established in October 2014. The procedure for blood drawing, labeling and testing was completed by December 2014. Staff education was completed by February 2015 with project rollout occurring in March 2015. Blood culture correlation was completed in May 2015 and CBC and type & screen correlation was completed in July 2015.

Measures: Staff kept track of all samples being obtained from the umbilical cord/placenta, including comments on difficulty to obtain sample, and success in obtaining a specimen. Additionally, feedback on the make up of the supply cart was provided to the team and changes made based on that feedback.

The samples from umbilical cord/placenta were then correlated with the paired samples from the newborn to compare bacterial cultures, type and screen and CBC with differential results.

Data: 75 infants had samples drawn from the umbilical cord/placenta to correlate with postnatal samples. This included 58 paired blood cultures and 54 paired CBCs and type and screens. The remaining samples were unable to be analyzed because of clotting of the umbilical cord/placenta sample, or inability to draw enough blood from the umbilical cord/placenta. Also following this abstract are 4 PDSA cycles from this project. We plan to generate a run chart for the poster to capture the feedback obtained with PDSA cycles to communicate changes that occurred regarding the method of obtaining blood from the umbilical cord and placenta.

Sampling: In reviewing process with nurses/NNPs drawing blood, the majority of successful blood draw were from a placental vein and not the umbilical vessels. Blood cultures: 55 blood cultures from both umbilical cord/placenta and baby were negative. There were 3 positive cultures from the umbilical cord/placenta:

<table>
<thead>
<tr>
<th>Blood culture source</th>
<th>Clinical condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Umbilical cord/placenta</td>
<td>Baby</td>
</tr>
<tr>
<td>E. Coli</td>
<td>Negative</td>
</tr>
<tr>
<td>H influenza</td>
<td>Negative</td>
</tr>
</tbody>
</table>
**Type and screen:** Positive antibody screens detected: 5 patients had a positive antibody screen in GEL with the peripheral blood sample and a positive antibody screen in GEL with the cord blood sample. In summary, the pattern of reactivity correlated between the peripheral blood sample and the cord blood sample in all 5 patients, and the strength of reactivity correlated between the peripheral blood sample and the cord blood sample, within 1 degree of reaction difference, in all 5 patients.

Negative antibody screens detected: 47 patients had a negative antibody screen in GEL with the peripheral blood sample and a negative antibody screen in GEL with the cord blood sample. In summary, all 47 of these patients had correlating results between peripheral blood sample and the cord blood sample.

**CBC and differential:** Please see the addendums following the discussion for the results of correlation studies. In summary, there was not good correlation between values for WBC, absolute lymphocyte/monocyte/neutrophil counts, platelets and hemoglobin.

**Discussion:** This project demanded the close collaboration of personnel in pathology, labor and delivery and the NICU. This process led to an even better understanding of the role that each team member plays, and an appreciation of these roles. The collaborative relationships between departments were enhanced by this process.

With respect to the actual blood sample acquisition, the majority of successful blood samples were from a placental vein and not the umbilical cord; this was likely due to the time needed to allow the Betadine prep to dry; this cord preparation was required to insure sterile sampling, and likely led to blood draining back into the placenta from the cord. This focused commitment to the process to insure accurate culture results likely contributed to only 1 sample being deemed a contaminant.

The blood culture correlation has led to the drawing of blood cultures from only the umbilical cord/placenta at birth on all babies admitted to the NICU beginning in May 2015; if a culture is positive, then the clinical team makes a clinical determination regarding the use of that information in correlation to the baby’s clinical condition.

Type and screens were found to consistently correlate, however, there was a very small sample of positive antibody screens. Therefore, it has been determined that if an infant with a positive antibody screen or DAT would require a colloid transfusion, an additional type and screen would need to be drawn from the infant. For all other infants, blood transfusions may now be ordered based on umbilical cord/placenta type and screen results.

Finally, after rigorous analysis of paired CBC’s, the conclusion was made that the WBC, hemoglobin and platelet count do not reliably correlate therefore necessitating the need for a CBC with differential and platelets to be drawn directly from the infant.

Ultimately, our institution met our goals within the defined time period and we were able to successfully correlate results when comparing blood cultures and type & screens from umbilical cord/placenta samples to postnatal samples, but a satisfactory correlation
did not occur with CBCs. As the blood culture and type & screen make up the majority of the phlebotomy losses upon admission to the NICU, we were pleased to initiate this process to all in-born NICU admissions as a way to reduce iatrogenic blood loss and minimize/eliminate arterial or venipuncture draws at admission. The next steps for our initiative will be to improve our umbilical cord/placenta blood sampling skills especially with smaller placentas, to continue to increase staff comfort with drawing time and workflow, and ultimately, to evaluate the hemodynamic stability and need for volume and/or pressor support in neonates admitted to the NICU prior to and after the initiation of this process of umbilical cord/placenta phlebotomy.

Team acknowledgement:
The authorship includes personnel from the NICU, OB, lab medicine, pathology and blood back. In addition to the authors, the rest of the NICU VO team at the University of Minnesota Masonic Children's Hospital includes Kenra Bruns, RN, Grace Doolittle RN, LC, Jennifer Helget RN, Ann Kvant RT, Janet Kubly Pharm D, Kimberly Popp RN, Beverly Rose RN.
Admission Labs from the Umbilical Cord Blood: The Procedure

Inclusion Criteria
1. Inborn
2. $\leq 27$ 6/7 weeks
3. $\leq 1250$ kg

Exclusion Criteria
1. Out-born
2. Placental Abruption
3. Multiple Gestation

SBAR:
1. To notify all OB and NICU staff of either the intended delayed cord clamping and/or UC blood draw. Delayed cord clamping is priority over UCB labs.
2. Determine with NICU resuscitation leader and OB provider if there is a need for chromosomes and cord gases collection prior to delivery.
3. NICU to determine which NICU team member will draw the UCB.

Process:

1. Placenta is delivered by Delivering provider to the sterile, stainless-steel basin.
2. Cord segments are collected and cut by current OB procedure for cord gases.
3. OB-RN notifies the NICU-RN that the placenta is ready for the remainder of the UCB collection.
4. Placenta must not leave the mother’s room or OR.
5. UCB cart is kept in NICU-storage room. Key for the cart is located on the side of the cart.
6. Procedure:
   a. Place chux over UCB-Cart. Place placenta bin on chux.
   b. With clean hands, don facemask with plastic eye shield and disposable gown, if not already on. Reapply clean gloves.
   c. Open sterile towel to create sterile field
      i. Open 21G safety needle or Butterfly needle (your choice), syringe 3-5 ml preferably (smaller syringes tend to draw more easily), and the purple transfer device (Saf-T Holder Blood Culture Device) onto the sterile field.
   d. Arrange lab-collection tubes on clean surface
   e. Briefly wipe top of blood culture vial with alcohol wipe and discard wipe.
   f. Prep betadine packet so that ends may be accessed with sterility.
   g. Don Sterile gloves
   h. Connect the syringe to the needle with maintenance of sterility
      i. Identify Umbilical vein
         i. Cords have three vessels
         ii. The umbilical vein is the largest of the three.
         iii. Can use large veins on placenta surface as well.
   j. Prep ~2 inches of the cord segment with 3 betadine swabs paying close attention to using friction AND allowing for it to dry for 2 minutes (a timer is provided for you, we suggest setting the timer for 3-4 minutes so that you do not have to break sterility).
Admission Labs from the Umbilical Cord Blood:
The Procedure

k. Stabilize the cord with your non-dominant hand and insert the needle with the bevel facing down into the umbilical vein away from your holding fingers and towards the placenta. (See Video)
l. Withdraw slowly on the plunger to aspirate required blood volume. Use gentle pressure so as not to create a vacuum. Minimum volume needed is:
   i. 2 mls for the blood culture
   ii. 2 ml into the purple EDTA tube (CBC and T&S (type and screen))
   iii. If chromosomes are needed, obtain 2 mls-1ml in a tall purple and 1ml in a tall green tube.
   iv. If goal volume (7ml) is not obtained, the following are to be prioritized:
      1. 1-3ml Blood culture
      2. 1ml purple EDTA tube
      3. May draw from secondary sites form the placenta in order to obtain required amount for T&S and chromosomes, however, blood culture must be from only one needle stick.
      4. Notify NICU provider of the minimum blood volume and which tubes were sent.
m. Withdraw the needle slowly as site may leak/spray when needle is withdrawn and engage needle safety mechanism
n. Attach syringe to the purple Saf-T Holder while maintaining sterility of connections.
o. Fill vials with required blood volume starting with the blood culture and continuing to use the purple Saf-T Holder for filling the remaining tubes.
p. Discard the needle and the purple Saf-T Holder into the sharps container.
q. Label the vials with the baby's label. You are responsible for making sure the baby's label matches the mother's label. Initial the labels and write CORD and the time on the label. A second healthcare worker needs to double check and initial the T&S label.
r. Return the placenta to the L&D RN with verbal notification that we are finished with it. Custody of the placenta is very important!!! If a placenta is misplaced, the State needs to be notified.

7. Discard any used materials and wipe down workspace with sani-wipe.
8. Return UCB-cart to the storage room lock and return key to side of cart.
9. Deliver the vials of blood to the NICU lab.
10. Notify NICU provider of the labs obtained and the labs that were not obtained, so that the correct labs can be ordered.
11. Record infant's name and labs that were drawn in the big pink binder along with any comments, concerns or ideas for improvement (only necessary during the validation period).

Logistics
- Cart will be restocked by the NICU NA
- Expiration dates will be check by the NA
- Extraneedles, syringes and Betadine will be stocked in addition to the pre-made kits.
Evaluation of Results

WBC was analyzed by methods Cord Blood and Peripheral to determine whether the methods are equivalent within Allowable Total Error of 15%. 42 specimens were compared over a range of 3.2 to 26.0 10^3/μL. The test Failed. The difference between the two methods was within allowable error for 13 of 42 specimens (31.0%). The average Error Index (Y-X)/TEa was 1.52, with a range of -2.29 to 7.43. The largest Error Index occurred at a concentration of 3.5 10^3/μL.

Key Statistics
Average Error Index: 1.82
Error Index Range: -2.29 to 7.43
Coverage Ratio: --

Evaluation Criteria
Allowable Total Error: 15%
Reportable Range: --

Deming Regression Statistics
Y = Slope * X + Intercept
Correlation Coeff (R): 0.8523
Slope: 1.114 (0.922 to 1.306)
Intercept: 1.00 (-1.57 to 3.58)
Std Error Estimate: 3.83
N: 42 of 42

Experiment Description

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<td>Result Ranges</td>
<td>3.2 to 26.0</td>
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<td>Mean ± SD</td>
<td>11.89 ± 6.30</td>
<td>14.26 ± 6.91</td>
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Signature: ____________________________  Copyright 1991-2014 Data Innovations, LLC
Sysmex/WBC Comparicon NICU Cord v Peripheral Printed: 24 Jun 2015  12:06.03  Page 1
Evaluation of Results

ALC was analyzed by methods Cord Blood and Peripheral Blood to determine whether the methods are equivalent within Allowable Total Error of 15%. 35 specimens were compared over a range of 0.7 to 9.6 10e9/L. The test failed. The difference between the two methods was within allowable error for 19 of 35 specimens (54.3%). The average Error Index (Y-X)/TEa was 2.17, with a range of -3.94 to 28.57. The largest Error Index occurred at a concentration of 0.7 10e9/L.

Key Statistics
Average Error Index 2.17
Error Index Range -3.94 to 28.57
Coverage Ratio --

Evaluation Criteria
Allowable Total Error 15%
Reportable Range --

Deming Regression Statistics
Y = Slope * X + intercept
Correlation Coeff (R) 0.3728
Slope 2.625 (1.743 to 3.509)
Intercept -6.60 (-10.69 to -2.32)
Std Error Estimate 4.45
N 35 of 35

Experiment Description

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<td>Result Ranges</td>
<td>0.7 to 9.6</td>
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<td>Mean ± SD</td>
<td>4.41 ± 1.76</td>
<td>5.67 ± 2.64</td>
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<td>Units</td>
<td>10e9/L</td>
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</table>
**Two Instrument Comparison**

**X Method: Cord Blood**

**Y Method: Peripheral Blood**

### Scatter Plot

- **Periphreral Blood (10e9/L)**
- **Cord Blood (10e9/L)**

### Error Index

- **Error Index, (Y-X)/TEa**
- **Cord Blood (10e9/L)**

### Evaluation of Results

AMC was analyzed by methods Cord Blood and Peripheral Blood to determine whether the methods are equivalent within Allowable Total Error of 15%. 35 specimens were compared over a range of 0.2 to 13.0 10e9/L. The test failed. The difference between the two methods was within allowable error for 6 of 35 specimens (17.1%). The average Error Index (Y-X)/TEa was 16.27, with a range of -5.53 to 470.00. The largest Error Index occurred at a concentration of 0.2 10e9/L.

### Key Statistics

- **Average Error Index**: 16.27
- **Error Index Range**: -5.53 to 470.00
- **Coverage Ratio**: --

### Evaluation Criteria

- **Allowable Total Error**: 15%
- **Reportable Range**: --

### Deming Regression Statistics

- **Y = Slope * X + Intercept**
- **Correlation Coeff (R)**: 0.0218
- **Slope**: 11.406 (7.355 to 15.456)
- **Intercept**: -18.23 (-29.64 to -6.82)
- **Std Error Estimate**: 25.82
- **N**: 35 of 35

### Experiment Description

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<td><strong>Mean ± SD</strong></td>
<td>1.77 ± 2.22</td>
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<td><strong>Units</strong></td>
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**Accepted by:**

**Signature**

**Date**

EP Evaluator 11.1.0.26

Sysmex/AMC Cord vs Peripheral Printed: 12 Jul 2015 11:04:48
Two Instrument Comparison

X Method: Cord Blood  
Y Method: Peripheral Blood

Scatter Plot

Error Index

Evaluation of Results

ANC was analyzed by methods Cord Blood and Peripheral Blood to determine whether the methods are equivalent within Allowable Total Error of 15%. 35 specimens were compared over a range of 0.3 to 14.0 10e9/L. The test Failed. The difference between the two methods was within allowable error for 5 of 35 specimens (14.3%). The average Error Index (Y-X)/TEa was 4.84, with a range of -2.01 to 62.67. The largest Error Index occurred at a concentration of 0.5 10e9/L.

Key Statistics

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<tr>
<td>Average Error Index</td>
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<tr>
<td>Error Index Range</td>
<td>-2.01 to 62.67</td>
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<tr>
<td>Coverage Ratio</td>
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Evaluation Criteria

| Allowable Total Error | 15%            |
| Reportable Range      | --             |

Deming Regression Statistics

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<th>Value</th>
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<tbody>
<tr>
<td>Y = Slope * X + Intercept</td>
<td>Correlation Coeff (R)</td>
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<td></td>
<td>Slope</td>
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Experiment Description

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Date:  

EP Evaluator 711.0.36  
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Page 1
Platelet Count

Two Instrument Comparison

X Method: Cord Blood
Y Method: Peripheral Blood

Evaluation of Results
Platelet Count was analyzed by methods Cord Blood and Peripheral Blood to determine whether the methods are equivalent within Allowable Total Error of 15%. 40 specimens were compared over a range of 23 to 317 10^9/L. The test Failed. The difference between the two methods was within allowable error for 18 of 40 specimens (<5%). The average Error Index (Y-X)/TEa was 3.00, with a range of -4.26 to 64.06. The largest Error Index occurred at a concentration of 23 10^9/L.

Key Statistics
- Average Error Index: 3.00
- Error Index Range: -4.26 to 64.06
- Coverage Ratio: --

Evaluation Criteria
- Allowable Total Error: 15%
- Reportable Range: --

Deming Regression Statistics
- Y = Slope * X + Intercept
- Correlation Coeff (R): 0.2598
- Slope: 0.394 (0.145 to 0.644)
- Intercept: 130.8 (74.9 to 186.6)
- Std Error Estimate: 59.5
- N: 40 of 40

Experiment Description

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<tr>
<td>Result Ranges</td>
<td>23 to 317</td>
<td>87 to 327</td>
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Evaluation of Results

Hemoglobin was analyzed by methods Cord Blood and Peripheral to determine whether the methods are equivalent within Allowable Total Error of 15%. 42 specimens were compared over a range of 10.2 to 17.3 g/dL. The test Failed. The difference between the two methods was within allowable error for 23 of 42 specimens (54.8%). The average Error Index (Y-X)/TEa was 0.86, with a range of -0.85 to 2.80. The largest Error Index occurred at a concentration of 12.4 g/dL.

Key Statistics
- Average Error Index: 0.86
- Error Index Range: -0.85 to 2.80
- Coverage Ratio: -

Evaluation Criteria
- Allowable Total Error: 15%
- Reportable Range: -

Deming Regression Statistics
- Y = Slope * X + Intercept
- Correlation Coeff (R): 0.5206
- Slope: 2.043 (1.470 to 2.617)
- Intercept: -13.46 (-21.92 to -5.01)
- Std Error Estimate: 2.86
- N: 42 of 42

Experiment Description

<table>
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<tr>
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<th>X Method</th>
<th>Y Method</th>
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<td>Exp Date</td>
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<tr>
<td>Result Ranges</td>
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<td>Mean ± SD</td>
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Accepted by: ____________________________

Signature

Date