Meeting of the NGSP Steering Committee
Minutes
Sunday July 15, 2012 3:00 PM – 5:30 PM
Westin Bonaventure, Los Angeles, CA

Participants:

*David Sacks —NIH, Chair, NGSP Steering Committee
*Randie Little—Univ. of MO, NGSP Network Coordinator
*Phillip Gillery—American Memorial Hospital (FR), IFCC Scientific Division
*Garry John—Norfolk and Norwich University Hospital (UK), Chair, IFCC Integrated Project on HbA1c
*Curtis Parvin—Bio Rad Laboratories
*Scott Reutten—Abbott Diagnostics
*Christine Flandre—Sebia
*Michael Steffes—University of Minnesota
*Hubert Vesper—CDC
*Cas Weykamp—Queen Beatrix Hospital (NL), IFCC Network Coordinator
***Member of the NGSP Steering Committee**

Susanne Adam—Roche Diagnostics
Shawn Connolly—Univ. Of MO, NGSP
Yuanfang Deng—Siemens
Mark Herlan—Roche Diagnostics
David Ikeda—Arkray
Ben Irvin—Bayer Diabetes Care
David Lacher—CDC/NCHS
Erna Lenters— Isala klinieken (NL)
Tony Prestigiacomo—Bio-Rad Laboratories
K. Ramadrishnan—ProdConcepts/AACC Ind. Div.
Violeta Raneva—ReCCS Japan
Curt Rohlfing—Univ. of MO, NGSP
Carla Siebelder—Queen Beatrix Hospital (NL)
Alexander Stoyanov—Univ. of MO
Takeshi Takagi—Arkray
Masao Umemoto—ReCCS Japan
Charles Xie—Bayer

Steering Committee members not present:
W. Greg Miller—Virginia Commonwealth University
David Nathan—Massachusetts General Hospital
William Roberts—ARUP Laboratories

1) **Welcome and Introduction—David Sacks, Chair, NGSP Steering Committee**
D. Sacks welcomed those in attendance, introduced new Steering Committee member Christine Flandre of Sebia, and thanked outgoing member David Simmons of Bayer Diabetes Care for his service to the NGSP. He noted that steering committee member William Roberts is gravely ill and expressed thoughts and wishes to him and his family. Those present introduced themselves.

2) **The 2011 Steering Committee minutes were approved by the members present.**

3) **NGSP Progress Report—Randie Little , NGSP Network Coordinator**
- NGSP Network Monitoring
  - The PRLs and SRLs continue to demonstrate excellent comparability.
  - One PRL is no longer participating so we now have two backup PRLs.
  - Monthly between-lab CVs for the NGSP network were generally <2% over the past year.
- Certification
  - The number of certified methods and laboratories has continued to increase.
  - There are currently 110 methods and 110 laboratories certified.
  - Most of the certified laboratories are Level 1 and outside the U.S.
  - There are issues with shipping to some countries.
  - We have seen a recent increase in the number of Level 2 laboratories, we are not sure what is driving this but it seems to be hospital labs that certify in groups (e.g. South Africa).
- CAP Data
  - The CAP data show much improvement in the comparability of HbA1c results in the field between 1993 and 2012.
  - Targets values for the survey are assigned by the NGSP SRLs.
  - 2012A Survey

- The method-specific means were all within 0.45 at all levels. Eight methods showed a bias >0.35% HbA1c (not all in the same direction).
- Method-specific, between-laboratory CV's ranged from 1.2% to 7.0%! All but 4 methods had CVs below 5% for all 3 HbA1c levels.
- Approximately 97% of laboratories were using methods that had between-lab CVs <5%. But only 20% of labs use methods with between-lab CVs <3% at all three levels.
- There appears to be room for improvement.
- Between-lab CVs by method type
  1) CVs for the ion-exchange methods were ≤3%.
  2) Several immunoassay methods also show very good performance with low CVs while others do not perform as well.
  3) CVs for the POC methods were not necessarily worse than those of lab methods.
  4) Several of the immunoassay methods with high CVs are used by very few labs but others are still used by a significant number of labs.
- Pass Rates
  1) Several ion-exchange and immunoassay methods as well as one POC boronate affinity method had pass rates of 100% at a level of 5.6% HbA1c.
  2) Most methods had pass rates >90%.
  3) Pass rates:

Specimen	NGSP Target (% HbA1c)	Acceptable Range (±7%)	Pass Rate % (Low/High)	Cumulative Pass Rate %	Cumul Pass Rate % (±6% Acceptable Range)
GH2-01	5.6	5.2-6.0	72.7/ 100	95.6	95.6
GH2-02	9.4	8.7-10.1	81.8/ 100	94.9	92.5
GH2-03	7.2	6.6-7.8	89.4/ 100	96.2	92.9

- Decrease in all-method CVs over time
  1) All-method CVs were ~5% in 2000
  2) The overall trend has been downward
  3) All-method CVs have hovered around 3.5-4.0% on the last several surveys.

Discussion:

D. Sacks asked if the labs certifying in these countries tend to be private or academic laboratories or both, R. Little said they seem to be a mixture of the two. D. Sacks noted that ~3400 laboratories now participate in the GH-2 survey, ~90% are within the U.S. C. Weykamp asked about the identical pass rates for the ±7% and ±6% limits for the low level sample. D. Sacks responded that the numbers are correct and this is due to the fact that CAP rounds the numbers in favor of the labs. RL noted that the all-method CVs seen in the latest CAP survey are comparable to what C. Weykamp sees in the IFCC monitoring program. P. Gillery asked what method types are being used in the U.S. and if there are any trends (e.g. from HPLC to immunoassay). R. Little said there are more immunoassay methods but ion-exchange methods remain popular. K. Ramadrishnan asked what followup is done for the ~5% of labs that fail the survey. R. Little responded that the NGSP does not know which labs pass or fail. D. Sacks said that labs are required by law to participate in PT, if a lab fails they are required to contact the CAP and explain why they failed and what corrective actions were taken. The consequences of failure depend upon whether the analyte is regulated or not: HbA1c currently is not, but will likely be at some point in the future. If a lab fails repeatedly they will fail their inspections and eventually they will not be allowed to perform the test. This all has nothing to do with NGSP but with federal regulations. Labs generally do not fail twice in a row. Compared with other surveys such as glucose the 5% failure rate is not unusual. Often a failure is not due to analytical error but some other error (e.g. transposition, results not submitted in time, etc.). K. Ramadrishnan asked about the scenario of a lab passing CAP but not NGSP given that NGSP has no jurisdiction. R. Little said there is no requirement for individual labs to obtain NGSP certification and only a small percentage do. It is for larger labs doing clinical trials, etc., it is costly so routine labs generally do not obtain certification. The way we monitor what is going on in routine clinical labs is via the CAP survey. G. John asked what the frequency of the survey is, D. Sacks responded that three HbA1c levels are sent twice a year. R. Little noted that there is also a CAP linearity survey and the NGSP now posts a summary of that data; participation is not required and a much smaller number of labs participate.

4) New NGSP Manufacturer Certification Criteria—Randie Little

- Current manufacturer certification criteria: 95% CI of the differences (between method and NGSP) must be within ±0.75% HbA1c.
- Current CAP criteria
  - Each result must be within ±7% of NGSP assigned target value
  - At 7% HbA1c, limit is 0.49% HbA1c
- Considerations in Choosing the New Certification Criteria
  - Fixed limits or percent:
    - Tighten to ±0.70% HbA1c (or tighter)
    - Use % limits as used for CAP grading
  - Comparison with CAP criteria
    - 2/3 or 3/3 passing on CAP
    - Within 7% (current), 6% (future)
  - Comparison with current certification criteria
  - Certification protocol
    - Single result or duplicates
- New certification criteria
  - Use percent rather than fixed criteria
    - Smaller % HbA1c limit at diagnostic and decision levels
    - Easier to compare with CAP criteria
  - Compare to 3/3 passing on CAP
    - We should expect labs to pass all 3 levels for optimal clinical value; 7% is reasonable at all levels
  - Comparison with current certification criteria
    - Should be more stringent, especially at critical levels
    - Should not be so tight as to fail too many methods
  - Use single results
    - Same as for patient care and diagnosis
    - Single results used for CAP survey
- New Manufacturer Certification Criteria
  - 37/40 results must be within ±7% of the NGSP SRL HbA1c; comparable to passing 3/3 on CAP (±7%)
  - Based on the past year's certification data, more than 95% of methods that passed with the current criteria would pass with the new criteria
- New Level 1 Laboratory Certification Criteria
  - 38/40 results must be within ±7% of the NGSP SRL HbA1c
  - Based on the past year's certification data, more than 93% of Level I laboratories that passed with the current criteria would pass with the new criteria

5) Other Issues: Randie Little

- The NGSP once again has grant funding, it is now obtained directly through NIDDK.
- There is a new NGSP SRL in Japan, ReCCs, directed by Dr. Masao Umemoto. They use the KO500 resin which is the Japan DCM for the IFCC comparisons.

6) Analyses and Comparisons of Certification Criteria: Curtis Parvin

- Current NGSP Criteria: 95%CI of the differences (between method and NGSP) must be within ±0.75% HbA1c (Note: at 7% HbA1c, limit is ~0.53% HbA1c)
- Analysis Approach: Current NGSP Criteria
  - 40 samples are tested in duplicate by the lab and a reference lab. The 95% CI is computed for the differences between lab and reference lab duplicate averages. If the 95% CI is within ±0.75% HbA1c the lab passes, otherwise the lab fails.
  - The CV of the average of duplicates for a reference lab is $CV = 100\sqrt{\sigma^2_{SRL} + \sigma^2_{DAY} + \frac{\sigma^2_{REP}}{2}} \Big/ \mu_{Samp}$
  - Based on past data the CV of the average of duplicates for a reference lab is set to 1.5%
  - Given Lab Bias (%) and CV (%) compute the probability that the lab fails the current NGSP criterion

- Computer simulation: 40 samples uniformly distributed based on the NGSP certification ranges were randomly generated, then the required CV/bias combinations required to pass the ±0.75% limit were determined based on 5%, 1% and 0.1% probabilities of failure. One million simulations were performed in order to obtain accurate estimates.

- CAP Criteria: Each result must be within ±7% of NGSP assigned target value (Note: at 7% HbA1c, limit is 0.49% HbA1c)
- Analytical Approach: CAP criteria
  - Simulation was not required, the criteria can be considered concentration independent so the estimates could be derived mathematically
  - 3 samples are tested by the lab. The assigned values are obtained from 7 SRLs testing each sample on 2 days in triplicate. If 2 or 3 of the lab's results are within 7% of the assigned values the lab passes, otherwise the lab fails.
  - CV of the assigned values for the average from 7 SRLs testing each sample on 2 days in triplicate is $CV = 100\sqrt{\frac{\sigma_{SRL}^2}{7} + \frac{\sigma_{DAY}^2}{7\times 2} + \frac{\sigma_{REP}^2}{7\times 2\times 3}} \Big/ \mu_{Samp}$
  - Based on past data the CV of the assigned values is set to 0.5%.
  - Given Lab Bias (%) and CV (%) compute the probability that the lab fails the CAP criterion
    - >1 of 3 lab results differ by >7% from their assigned values (CAP 2/3)
    - ≥1 of 3 lab results differ by >7% from their assigned values (CAP 3/3)
- Analysis Approach: New NGSP criteria
  - 40 samples are tested once by the lab and in duplicate by a reference lab. If N (N = 37 or 38) or more of the lab's 40 sample results are within 7% of the reference lab's average value then the lab passes, otherwise the lab fails.
  - As before, based on past data the CV of the average of duplicates for a reference lab is set to 1.5%
  - Given Lab Bias (%) and CV (%) compute the probability that
    - ≤3 of 40 lab results are >7% from the reference averages (NGSP 37/40)
    - ≤2 of 40 lab results are >7% from the reference averages (NGSP 38/40)
- Comparing Different Criteria
  - Determine contours for combinations of lab bias and CV that give a specified probability of failing a given criterion
    - Contours for failure rates of 0.1%, 1%, and 5%
    - Overlay the contours to compare criteria
- Results
  - Current NGSP vs. CAP 2/3 within 7%
    - For bias and CV combinations that have a 1% chance of failing CAP, the probability of failing the current NGSP criterion is also about 1%.
    - For bias and CV combinations that have a 5% chance of failing CAP, the probability of failing the current NGSP criterion is >5%
    - For bias and CV combination that have a 0.1% chance of failing CAP, the probability of failing the current NGSP criterion is <0.1%
  - Current NGSP vs. CAP 3/3 within 7%: CAP (3/3) within 7% is more difficult to meet than the current NGSP criterion.
  - NGSP 37/40 single examinations vs. CAP 3/3 within ±7% of reference average
    - For bias and CV combinations that have a 5% chance of failing CAP, the probability of failing an NGSP criterion that requires ≥37 of 40 single results to be within ±7% of the reference averages is also about 5% when bias is near zero. For larger bias the probability of failing the NGSP criterion is >5%
    - For bias and CV combination that have a 1% (or 0.1%) chance of failing CAP, the probability of failing the NGSP criterion is <1% (or <0.1%) for bias near zero, but >1% (or >0.1%) for larger bias.
  - NGSP 38/40 single examinations vs. CAP 3/3 within ±7% of reference average
    - For bias and CV combinations that have a 1% (or 0.1%) chance of failing CAP, the probability of failing an NGSP criterion that requires ≥38 of 40 single results to be within ±7% of the reference averages is also about 1% (or <0.1%) when bias is near zero. For larger bias the probability of failing the NGSP criterion is >1%

- For bias and CV combination that have a 5% chance of failing CAP, the probability of failing the NGSP criterion is >5%.

Discussion:
M. Herlan asked whether there has been any further consideration of changing the range for certification samples to focus more on the diagnostic range and less on the very low and high ranges. R. Little responded that the range is still the same, 4-10% HbA1c. The new criteria will focus more on being tighter in the low ranges. D. Sacks added that the range of 4-4.5% HbA1c is probably not clinically relevant but there is increasing evidence that HbA1c differences between 5 and 6 are clinically relevant; it is important that HbA1c measurements be accurate within this range. RL noted that it is unusual to see samples with HbA1c levels below 4.5%. K. Ramadrishnan noted that there could be a scenario where a method passes the new criteria even though three samples are out in the same part of the range (e.g. the low end of the range) indicating a bias with the assay in that part of the range. C. Parvin said that these calculations do not account for this, they assume a constant CV across the range. S. Ruetten asked about the significance of coutour lines being close together vs. far apart. CP responded that if the lines are close together this means a small change in CV or bias would mean a large change in the probability of passing or failing. C. Weykamp noted that NGSP samples are single-donor while the CAP samples are pooled; pooled samples tend to show less variability in method comparisons. However, it is unclear how this could be factored into the calculations. C. Rohlfing said that this would probably have some effect on the estimates but not much. D. Sacks added that if anything this would make it more difficult to pass NGSP than the calculations indicate, and it is appropriate for the NGSP criteria to be more stringent than CAP, this was generally agreed. D. Lacher asked if the assumption of constant CV across the range of values is reasonable. R. Little and C. Parvin responded that although different methods may vary somewhat in terms of the relationship between level and variability this is a reasonable assumption. C. Parvin added that with laboratory analytes the relationship is often somewhere between constant CV and constant bias. M. Herlan said that the bias is often not constant throughout the range, but some assumptions must be made to perform the analyses. C. Parvin noted that at least now there is some objective way of comparing the criteria. D. Lacher asked what would be done if 3 out of 40 samples failed and they were not randomly distributed, e.g. they were all analyzed on the same day. What would be done in this case, would they be excluded? M. Herlan said that if there is a bias within a specific concentration range a method would be more likely to fail with individual samples vs. pools.

7) Clinical Advisory Committee Meeting Update—David Sacks

- The CAC is composed of representatives from major clinical diabetes organizations. The purpose is to facilitate interchange between these organizations and the NGSP.
- The CAC met at the ADA in June 2012.
  - R. Little presented an update on NGSP progress and discussed interference from hemoglobin variants.
  - R. Little spoke about the effects of renal failure on HbA1c and the possible role of glycated albumin in these patients.
  - D. Sacks gave an overview of the CAP criteria and spoke about the reporting of HbA1c outside of the U.S.
  - D. Sacks addressed the topic of HbA1c for diagnosis and gave an update on the reporting of estimated average glucose (~36% of labs that participate in CAP state that they are reporting eAG but we do not know how many samples each of the individual labs analyzes).
  - Judy Fradkin of the NIDDK discussed their HbA1c fact sheet intended for patients.
  - Len Pogach spoke about HbA1c use at the VA. They are trying to coordinate HbA1c reporting at all of their hospitals.

8) NHANES—David Lacher

- NHANES is a cross-sectional survey performed by the National Center for Health Statistics which is part of the CDC.
- Survey ~5000 people/year
- HbA1c is one of a number of diabetes tests in the survey

- During 2005-2008 we saw the mean HbA1c move up ~0.14% HbA1c
  - Caused concern because it bumps up the prevalence of pre-diabetes
  - FPG and 2-hour PG did not show the same trend
  - Looked at various subgroups (race/ethnicity, age groups, BMI categories, etc.) and saw the trend in HbA1c across all groups
  - We generally suspect a method problem in these cases, but we can also have survey design effects due to changes in sampling. The statisticians generally account for this with weighting, etc., but we can still have "pockets" where the population sampled causes a bias
  - We went over all of the data for the assay method including internal QC, proficiency testing, NGSP, etc. and could not find evidence of assay bias.
  - One question was if the NGSP system is sensitive enough to detect a difference this small, our general impression after discussions with the NGSP was that it may not be able to.
  - We looked at other epidemiological surveys using the same lab to see if they saw a similar pattern in HbA1c and they did not. However, they were different types of studies than NHANES.
  - In the end we could not come up with a solid answer.
  - We initially pulled the data but put it back out after the investigation
  - We will continue to follow this, including performing statistical modeling with HbA1c as the dependent variable and various independent variables (lab tests, demographics, etc.) and do analyses relating to cycle year.
  - In the epidemiology world these small differences matter even though they may not in the clinical world.
  - We will be publishing a paper on our analyses.

Discussion:
D. Sacks said that the NHANES issue re-emphasizes the importance of the work that NGSP does. K. Ramadrishnan noted that NGSP was used as a model in an industry workshop on standardization. D. Lacher said that for NHANES they try to use methods that are standardized, NHANES is also a resource because of the pristine samples that are collected, we assist groups involved in standardization.

9) CAP Survey—David Sacks

- Change in acceptable limit
  - CAP changed from peer-group grading for the whole blood HbA1c survey to accuracy-based grading using the NGSP target in 2007.
  - The initial limit was ±15%, this has subsequently been tightened and is now ±7%.
  - Manufacturers wanted to know what the eventual goal was, CAP subsequently decided that the eventual goal was ±6%
  - Labs have been informed of whether they would have passed or failed at ±6% on their CAP reports for several years.
  - Last month at the CAP meeting I presented the new NGSP criteria, based on this and analyses of failure rates at ±6% CAP decided it will go to ±6% next year.
- Uncertainty of CAP value assignments—Manufacturers have requested that the uncertainty of the CAP target value assignments be made public, the NGSP will begin including this on the CAP reports and/or the NGSP web site.

Discussion
K. Ramadrishnan asked if there are any matrix issues with the CAP samples. D. Sacks responded that the CAP GH-2 survey samples, as well as NGSP samples used for certification and monitoring, are all whole blood so there are no matrix effects.

10) IFCC Integrated Project Update—Garry John

- After the tasks they had been assigned to had been successfully completed the IFCC Working Group on HbA1c Standardization was disbanded.

- Subsequently the IFCC Integrated Project was formed to monitor and help implement global standardization of HbA1c.
- The IP works across all divisions of the IFCC.
- G. John attended consensus meeting in association with the IDF meeting in Dubai last year.
  - Updated consensus statement
    - Reinforced dual reporting (but recognises that some countries will not adopt this)
    - Encourages journals to ask for dual reporting in publications
    - Establish web based calculator for conventional results
    - Next IDF meeting (Australia) dual reporting in posters
    - Workshops to explain the value of standardisation in countries where it is limited or does not exist
- Presentations scheduled for later this year:
  - Brazilian Congress of Clinical Pathology and Laboratory Medicine
  - IDF Western Pacific Meeting
- Met with the president of the Japanese Diabetes Society earlier this year and obtained an understanding of how Japan will be reporting HbA1c.
- We are preparing a review article on HbA1c based around the history, present situation and future use of HbA1c.
- Sent out a HbA1c questionnaire to all IFCC member countries.
  - Due to an error that occurred when the survey was transferred to the internet we do not currently know which countries responded, we are trying to identify them based on IP addresses.
  - 40 countries responded
  - Survey questions
    - Is HbA1c widely available in your countries? (95% Yes, 5% No)
    - Is testing mainly performed in laboratories (70%), POCT (0%), both (30%)?
    - Are the assays calibrated? (92.5% Yes, 7.5% No)
    - If calibrated, by IFCC (45.7%), NGSP (34.3%), Unknown (20%)?
    - How are results reported? SI (mmol/mol) (10%), NGSP(%) (55%), both (35%)
    - How will results be reported in the future? SI (38.9%), NGSP (25%), both (36.1%)
    - What date will the change be implemented? (Wide range of responses)
    - Is there national QA or proficiency testing? (59% Yes, 41% No)
    - How often is EQA performed? (Ranged from 1x/year to monthly)
    - How many samples per distribution? (Ranged from one to five)
    - What type of material is used for EQA? (Processed liquid 11.8%, processed lyophilized 35.3%, whole blood 52.9%)
    - Are target values assigned? (Yes 90.5%, No 9.5%)
    - How are target values assigned? (Responses varied)
    - Do you currently use HbA1c for diagnosis? (Yes 40.6%, No 59.4%)
    - If not are there plans to use HbA1c for diagnosis (Yes 65%, No 35%)
    - If yes to either previous question will you use only 48 mmol/mol (6.5%) for diagnosis? (Yes 76.2%, No 23.8%)
    - Will other cutoffs be used (Responses varied)
    - Would you be willing to answer additional questions arising from these responses (Yes 87.1%, No 12.9%)
  - Concerns
    - Lack of EQA
    - Lack of standardization in some countries
    - Do countries that are targeting HbA1c for diagnosis have processes in place that make this possible?

Discussion:
D. Sacks noted that there is a calculator on the Swedish Society for Clinical Chemistry web site to facilitate conversion between units, and one will be posted on the NGSP web site soon which will convert between IFCC mmol/mol, NGSP % and eAG. There will also be a separate units converter

for change or sd. Diabetes Care is planning to require dual reporting for HbA1c, Diabetelogia is planning to do this as well. Garry John noted that Diabetic Medicine already requires this.

11) JCTLM Meeting regarding HbA1c Listings—Randie Little

- JCTLM held a meeting July 14 to clarify their listings for HbA1c reference methods and materials.
- The NGSP CPRL/DCCT reference method has been listed for a long time
- The IFCC reference method is also listed as is a subsequent modification of the IFCC RM
- There was confusion over what the various methods measure (mass fraction, peak area fraction, etc.), also there were questions over what the methods report and the listings for reference materials.
- There is information that needs to be added to the listings.
- There were questions as to whether a recently-developed IDMS reference method that uses synthesized hexapeptides is of a higher order than the current IFCC reference method.
- There is also a question of defining what traceability means
  - Do values reported for clinical care have to be reported in the same units as the higher order reference method?
  - In clinical care consistency of results over time is the most important concern.
  - R. Little asked them what group decides what numbers will be reported in patient care, no one seemed to know, there is still confusion over this.
  - If units reported by reference methods changes as methods improve does this mean the units reported for clinical care must change as well? If so this could have a negative impact on patient care.

Discussion:

C. Weykamp said that the president of the IFCC made it clear that the units for reporting HbA1c in clinical care will not change in the future. The decision regarding the new IDMS reference method was that the listing request will be withdrawn while the method is further investigated. There has only been one comparison with the current IFCC RM and the data was only generated in one lab. H. Vesper noted that another question revolved around the definition of the measurand, the method claims to measure HbA1c but it uses hexapeptides as calibrators. R. Little said that reference materials listed can be used by reference methods or by routine methods, this is defined in their certificate of analysis.

12) HbA1c for Diagnosis: Meeting—David Sacks

- The ADA has endorsed the use of HbA1c for diagnosis, but the FDA currently does not allow any manufacturers to put a diagnosis claim on their package inserts since the claim was not originally stated when the methods were approved.
- We have been trying to get a meeting between manufacturers and the FDA arranged so that the requirements for a diagnosis claim can be better defined.
- Advamed has organized an open meeting that will take place August 16 in Washington DC.
- Goal is to facilitate communication between the manufacturers and the FDA and hopefully assist the FDA in developing reasonable criteria for a diagnostic claim.

Discussion:

R. Little expressed concern that the number of samples the FDA will require for checking interferences from hemoglobin variants may not be sufficient. D. Sacks said that he has attended FDA meetings and his sense is that they want to gather information and learn, they will likely not present criteria at the meeting. H. Vesper noted that FDA often defers to CLSI guidelines so it might be helpful if a guideline for HbA1c performance required in diagnosis was put together.

D. Sacks thanked everyone for their attendance, the meeting was adjourned at 5:25 PM.

Minutes prepared by C. Rohlfing 7/27/2012. Modified by R. Little 7/31/2012 and D. Sacks 08/08/2012.