CEM

ORACLE

Better Moisture/Fat Analysis

Original Scope

Design Goal:

Create a universal fat system that removes the bottlenecks and limitations of reference chemistries and rapid techniques. Design a rapid system that no longer requires any form of method development.

Long-term vision:

To become the standard reference technique for fat testing worldwide

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What is the ORACLE?

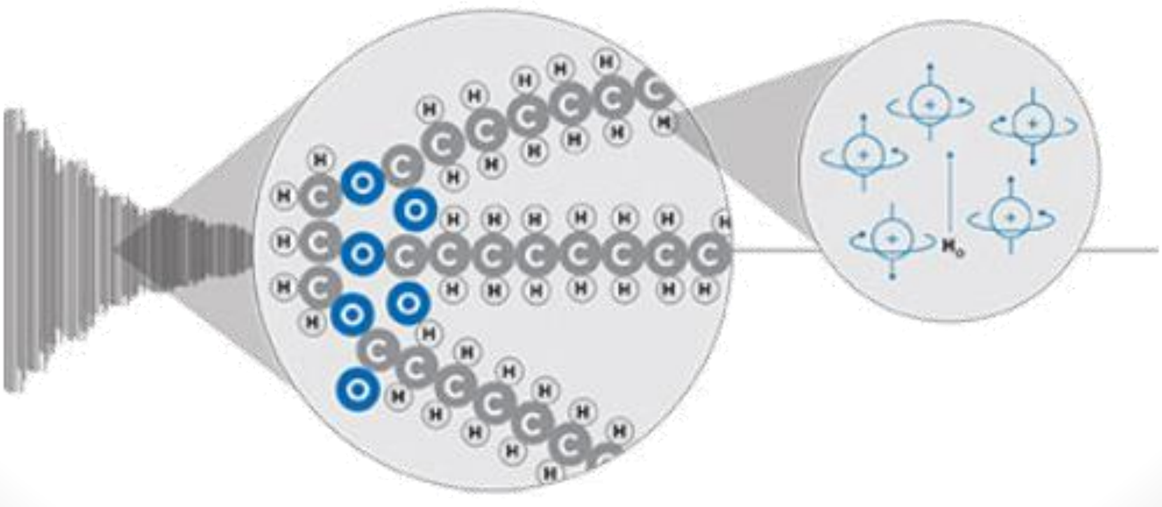
- First and only Universal Fat Analyzer
  - Rapid NMR that requires NO fat method development
- Accurately analyzes moisture and fat in ANY unknown food sample

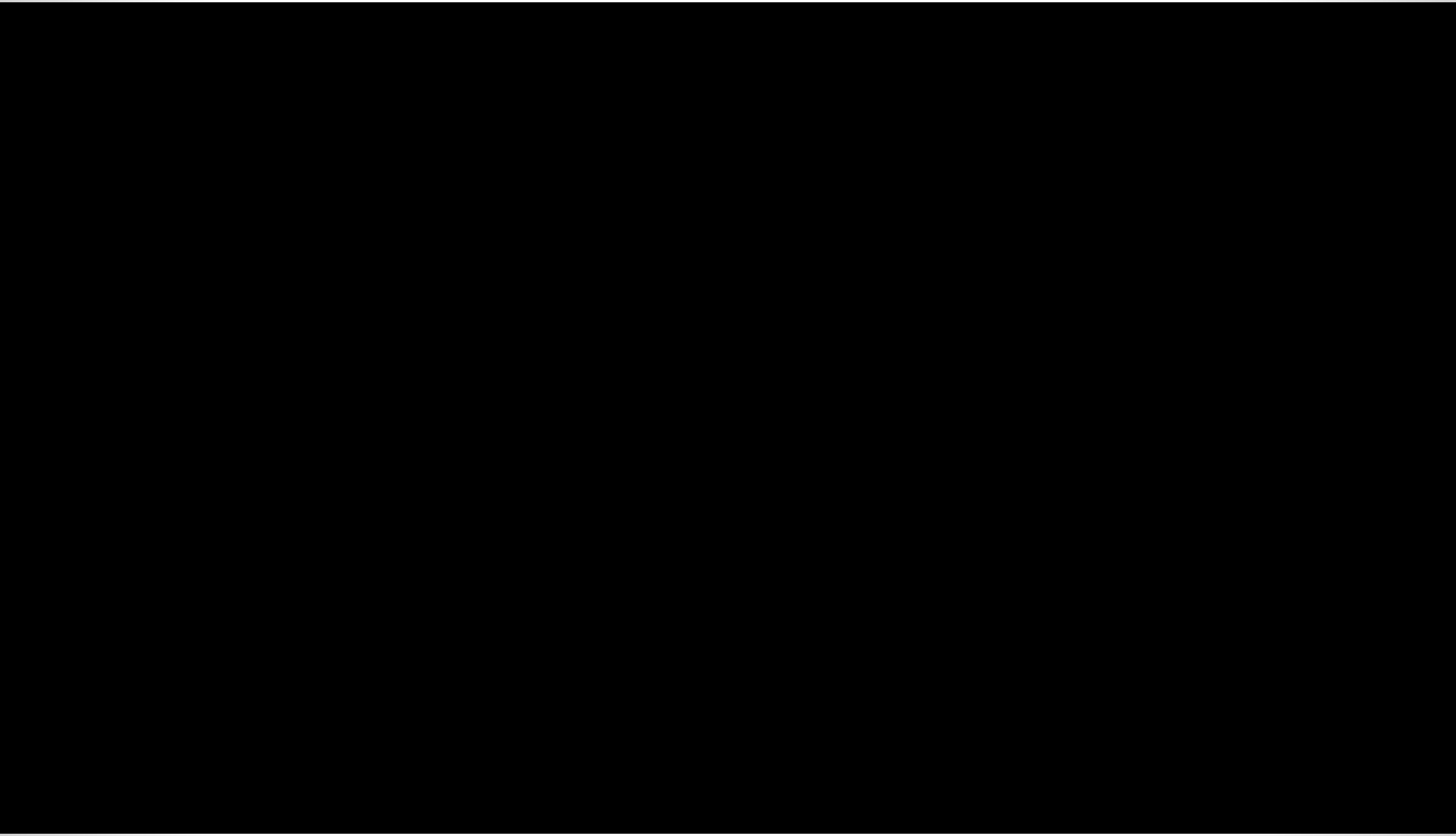
How the ORACLE works

1. Send a radio frequency signal that interacts with the H^+ protons on the sample's fat molecules

2. Sends the protons to an excited state

3. Protons relax to their natural state, releasing energy which is equated to fat content





ORACLE vs other NMR

The ORACLE utilizes a breakthrough NMR technology developed by CEM that overcomes the deficiencies of previous NMR technologies.

Two improvements over Trac technology

1. Isolates detection of proton signals on fat molecules from all other sample components

2. Eliminates partial decay signals of varying fat molecules

Validation of Technology

- ~30 CRM's analyzed on ORACLE
  - Samples extensively tested in collaborative studies (typically 10+ certified laboratories)

- CEM outsourced 100's of samples to Eurofins and Silliker
  - Submitted samples in "blind" and "non-blind" fashion to capture true sample variability

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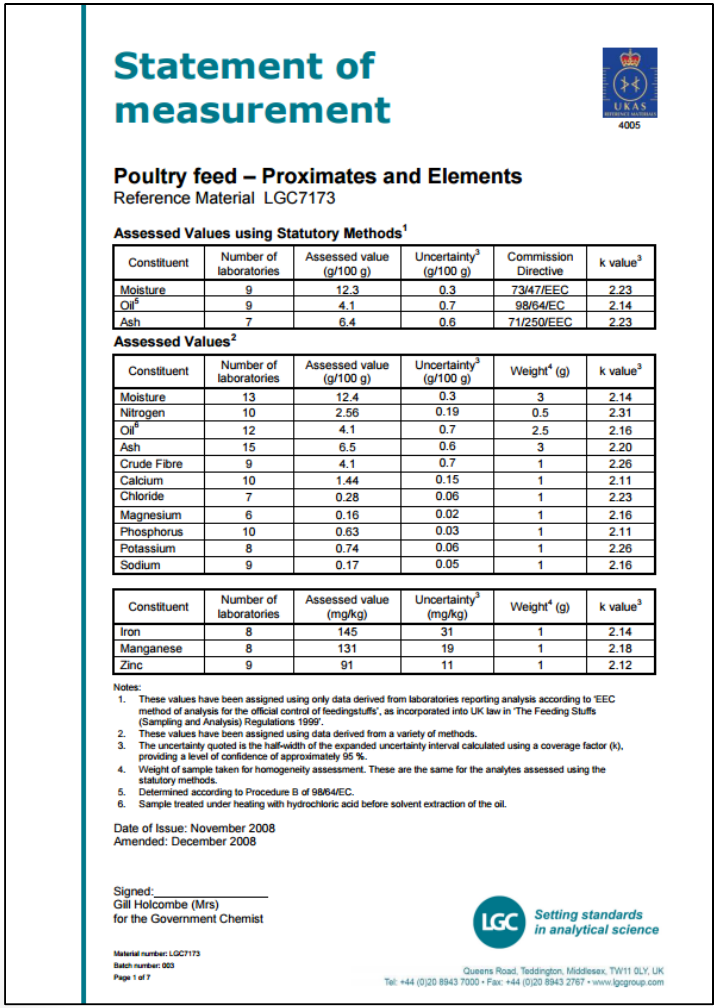
Certificate of Analysis (COA)



Statement of measurement

4005

Poultry feed – Proximates and Elements
Reference Material LGC7173

Assessed Values using Statutory Methods[1]

Constituent	Number of laboratories	Assessed value (g/100 g)	Uncertainty[3] (g/100 g)	Commission Directive	k value[3]
Moisture	9	12.3	0.3	73/47/EEC	2.23
Oil[5]	9	4.1	0.7	98/64/EC	2.14
Ash	7	6.4	0.6	71/250/EEC	2.23

Assessed Values[2]

Constituent	Number of laboratories	Assessed value (g/100 g)	Uncertainty[3] (g/100 g)	Weight[4] (g)	k value[3]
Moisture	13	12.4	0.3	3	2.14
Nitrogen	10	2.56	0.19	0.5	2.31
Oil[6]	12	4.1	0.7	2.5	2.16
Ash	15	6.5	0.6	3	2.20
Crude Fibre	9	4.1	0.7	1	2.26
Calcium	10	1.44	0.15	1	2.11
Chloride	7	0.28	0.06	1	2.23
Magnesium	6	0.16	0.02	1	2.16
Phosphorus	10	0.63	0.03	1	2.11
Potassium	8	0.74	0.06	1	2.26
Sodium	9	0.17	0.05	1	2.16

Constituent	Number of laboratories	Assessed value (mg/kg)	Uncertainty[3] (mg/kg)	Weight[4] (g)	k value[3]
Iron	8	145	31	1	2.14
Manganese	8	131	19	1	2.18
Zinc	9	91	11	1	2.12

Notes:
1. These values have been assigned using only data derived from laboratories reporting analysis according to 'EEC method of analysis for the official control of feedingstuffs', as incorporated into UK law in 'The Feeding Stuffs (Sampling and Analysis) Regulations 1999'.
2. These values have been assigned using data derived from a variety of methods.
3. The uncertainty quoted is the half-width of the expanded uncertainty interval calculated using a coverage factor (k), providing a level of confidence of approximately 95 %.
4. Weight of sample taken for homogeneity assessment. These are the same for the analytes assessed using the statutory methods.
5. Determined according to Procedure B of 98/64/EC.
6. Sample treated under heating with hydrochloric acid before solvent extraction of the oil.

Date of Issue: November 2008
Amended: December 2008

Signed:________________
Gill Holcombe (Mrs)
for the Government Chemist

Setting standards in analytical science

Material number: LGC7173
Batch number: 003
Page 1 of 7

Queens Road, Teddington, Middlesex, TW11 0LY, UK
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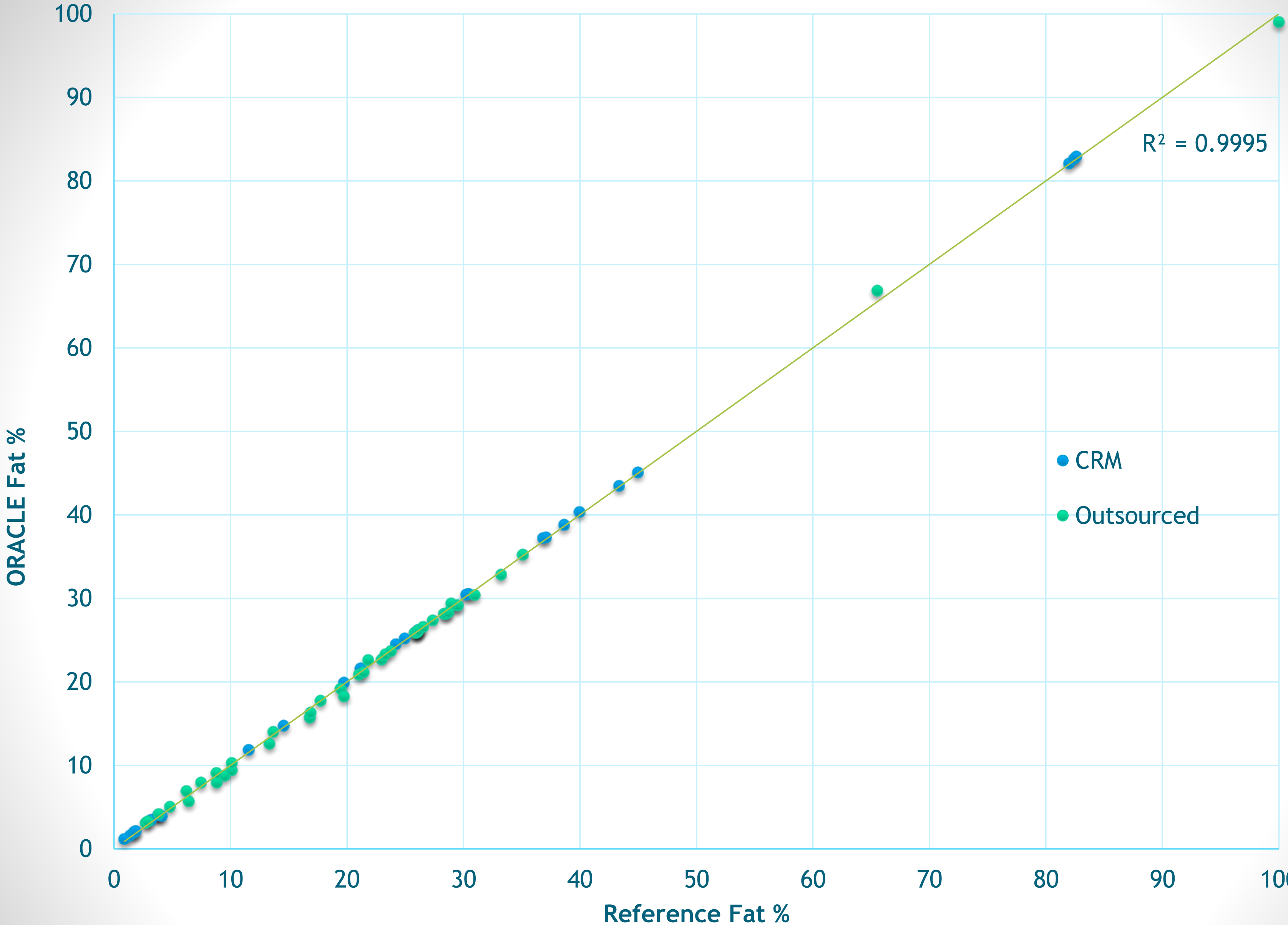
- Accompanies every CRM sample
- Information varies slightly based on where it was sourced (e.g. Muva Kempten vs. NIST)
- Assessed values for determined components (e.g. fat/oil, moisture, protein, ets)
- Explanation of Statistics
- Suggested sample sizes
- Handling/Preparation instructions
- Shelf life

CRM Samples Run on ORACLE

Sample	Source	% Fat	+/-
Wheat Flour	LGC	1.39	0.17
Processed Meat	LGC	11.57	0.44
Poultry Feed	LGC	4.10	0.70
Sweet Digestive Biscuit	LGC	21.17	0.45
Powdered Infant Formula	NIST	30.43	0.95
Cream Powder	Muva Kempten	43.39	0.15
Whole Milk Powder	Muva Kempten	26.14	0.11
Salted Butter	Muva Kempten	82.00	0.78
Butter	Muva Kempten	82.43	0.12
Butter	Muva Kempten	82.62	0.82
Fresh Cheese (Lact. Red.)	Muva Kempten	24.19	0.38
Processed Cheese	Muva Kempten	14.58	0.18
Fresh Cheese	Muva Kempten	3.84	0.26
Heavy Cream	Muva Kempten	38.65	0.15
Heavy Cream	Eurofins	30.23	0.05
Heavy Cream	Eurofins	37.09	0.03
Heavy Cream	Eurofins	44.98	0.09
UHT Milk	Muva Kempten	1.71	0.01
Milk (Past. Homog.)	Eurofins	0.89	0.01
Milk (Past Homog.)	Eurofins	1.84	0.01
Milk (Past Homog.)	Eurofins	3.19	0.02
Yogurt	Muva Kempten	1.87	0.05
Yogurt	Muva Kempten	3.80	0.05
Boiled Sausage	Muva Kempten	19.75	0.36
Heavy Cream	Eurofins	36.83	0.11
Parmesan Cheese	Muva Kempten	24.98	0.12
Milk Chocolate	Muva Kempten	39.98	0.42

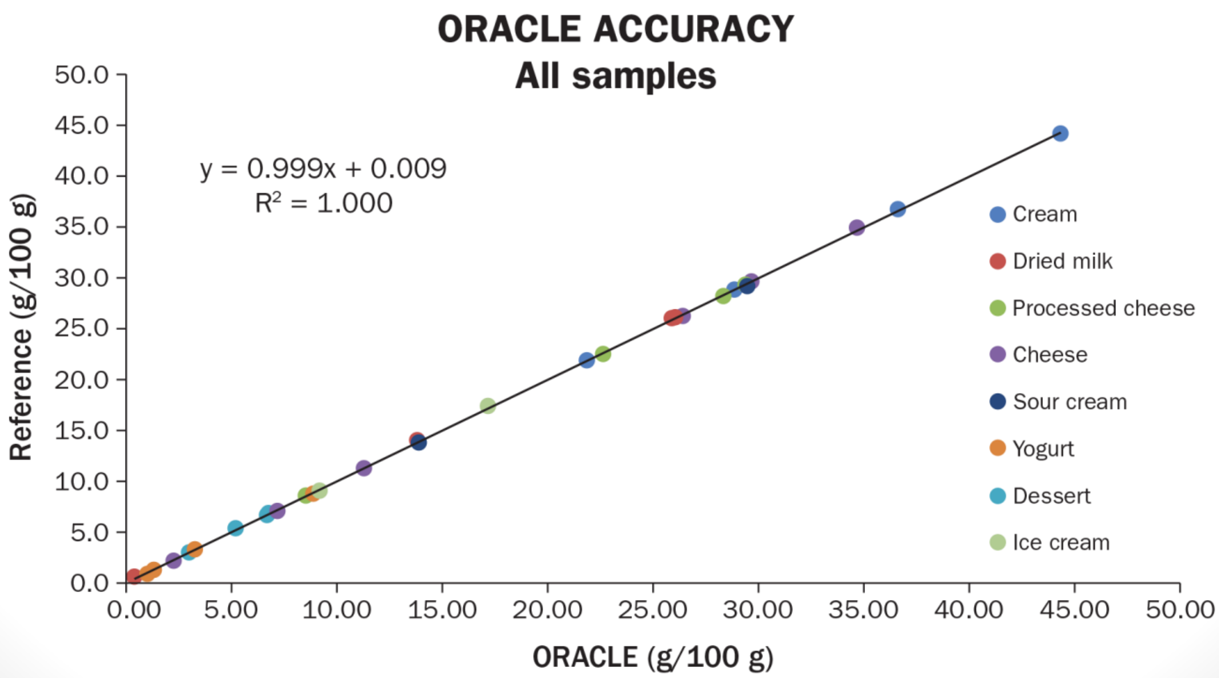


ORACLE Fat %
Reference Fat %
R² = 0.9995
CRM
Outsourced
0
10
20
30
40
50
60
70
80
90
100

ORACLE Actalia Study

Further Validation from Actalia

- Actalia is a COFRAC accredited lab in France
  - Validates equipment for the dairy industry
  - Highly respected by ISO and IDF
    - Seen as “experts” in dairy analysis



Actalia Study

- 2 major conclusions from ORACLE testing

1. The ORACLE "..reproducibility is lower than [better than] the reproducibility of the reference method."

2. The accuracy of the ORACLE compared to reference chemistry showed the "…regression slope (0.999) and the intercept (0.009) are not significantly different, respectively from 1.00 and zero (P=5%)."

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Actalia Importance

- Accredited, respected third party company tested and approved the ORACLE as:
  - Accurate
  - Repeatable
  - Easier than Reference Chemistry

- This data shows ORACLE can replace both:
  - Reference Chemistry (mojonnier, gerber, etc)
  - NIR/FT-IR (no calibrations, accuracy = more $$)

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ORACLE and AOAC

Is the ORACLE AOAC Approved???

- Short Answer: Yes!!
- Long Answer:
  - AOAC does not approve UNITS, only technology/methods
  - AOAC 2008.06 and PVM 1:2004 are approved methods using “Rapid determination of moisture/solids and fat in meat/dairy products by MW and NMR analysis”
  - ORACLE uses MW and NMR, so it is still an approved method

AOAC 2008.06
Fat and Moisture in Meat and Processed Meat

- Ground beef
- Chicken
- Turkey
- Pork
- All beef hot dogs
- Ham
- Pork sausage
- Potted meat

AOAC PVM 1:2004
Fat and Moisture in Dairy Products

- Milk
- Cream
- Ice cream mix
- Yogurt
- Sour Cream
- Cheese
  - Mozzarella
  - Swiss
  - Cheddar
- Cream Cheese

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Using the ORACLE

Two Ways to Operate

Rapid- SMART 6

- Process control labs that need rapid moisture & fat results
- Results = < 5 minutes
- Dry samples in the SMART 6 for moisture results and then analyze fat in ORACLE

High Throughput- Oven

- Testing labs running 50+ samples per day
- Dry samples overnight in oven
- Condition 1 hour in CEM Precision Heater Block and then analyze fat in ORACLE

SMART 6 + ORACLE Procedure

SMART 6 Moisture Analysis
2-4 minutes

Condition in QuikPrep
<45 seconds

ORACLE Fat Analysis
30 seconds

Air Oven Testing Sequence

Dry in Oven
Overnight

Condition in Heater Block
30-60 minutes

ORACLE Fat Analysis
30 seconds

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ORACLE R&D Lab Benefits

- Removes the variability of reference testing, especially for blended products
- Gives users the ability to “blindly” test new or modified samples with confidence
- No need for revalidation of methods after product reformulations
- Differences in sample matrices have no effect on ORACLE accuracy

Global Repeatability

- All ORACLEs are designed to produce the same NMR signal
- Ensures consistent results across suppliers and manufacturers worldwide

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OEM

ORACLE vs Everything

ORACLE Alternatives

- Reference Chemistry
  - Soxhlet, Mojonnier, Gerber, etc
- NIR/FT-IR
  - FOSS, Bruker, Perten
- SMART Trac
  - Old CEM Technology

Reference Chemistry

USDA Paper on Reference Testing

- USDA study on Reference Chemistry performance by Contract Labs
  - In general poor results, with 30-50% of results outside 1 St Dev
  - Shows the need to "question" reference chemistry

Reference materials to evaluate measurement systems for the nutrient composition of foods: results from USDA's National Food and Nutrient Analysis Program (NFNAP)

Class	Nutrient	Total CRMs	Total labs	Total values	Count of 0 to |1|	Count of |1| to |2|	Count of |2| to |3|	Count of >|3|	Percent > |2|	Percent >|3|
Proximates	Moisture	11	7	118	82	22	9	5	11.9	4.2
	Protein	9	5	106	60	24	12	10	20.8	9.4
	Ash	11	5	107	55	26	11	15	24.3	14.0
	Total Fat	11	6	129	52	39	15	23	29.5	17.8

Reference Chemistry Woes

Milk Powder		GC FAMES	Base Hydrolysis	Sohxlet	Roese Gottlieb	Blight and Dyer
Total Fat (g/100g sample)	Mean	27.39	25.25	28.42	24.94	24.41
	SD	2.22	0.41	0.2	0.44	0.52
	%RSD	8.11	1.65	0.7	1.76	2.13

Aued-Pimentel et al. *Quim. Nova*, 2010, 33, 76 – 84

- Using the wrong reference extraction can lead to the wrong %Fat result
- “Mixed” samples containing various sample matrices are extremely difficult to extract properly
    - Never a problem for the ORACLE

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Actalia Study

- 2 major conclusions from ORACLE testing

1. The ORACLE "..reproducibility is lower than [better than] the reproducibility of the reference method."

2. The accuracy of the ORACLE compared to reference chemistry showed the "…regression slope (0.999) and the intercept (0.009) are not significantly different, respectively from 1.00 and zero (P=5%)."

Negatives of Chemical Extractions

- High Cost
  - Chemicals, disposal, labor, consumables, and more
- Safety Issues
  - Uses various hazardous solvents and exposed hot surfaces such as air ovens and hot plates
- Time per Test
  - Modified methods can take 15-20 minutes, full methods can take up to 16 hours
- Difficulty of SOP
  - Multiple opportunities for human error leading to poor repeatability and reproducbility

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NIR and FT-IR

Moisture, Fat, SNF, and Protein

ORACLE Rapid Moisture/
Solids and Fat Analyzer

Sprint Rapid Protein Analyzer

- Better Accuracy than NIR and FT-IR technology
- No calibration maintenance or cost
- Typically 1 method for many products

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Dairy Production Needs

CEM Recommended <u>Equipment</u>

- ORACLE (M/F), Sprint (P)

<u>Products Tested</u>

Milk
Cream
Liquid Whey
Cheese
Whey Powder
Milk Powder
Retentate
Condensed Milk
UF Milk
Additives
Ice Cream
Yogurt

FOSS Recommended <u>Equipment</u>

- FT120 (liquid) FoodScan (solid) NIRS DS2500 (powder)

*

*FoodScan can analyze powders but accuracy will be worse

Using AOAC to compare data

- AOAC data is unbiased, performed by certified laboratories
  - The best representation of true system accuracy
- CEM has Dairy AOAC approval for many products
  - FOSS only has AOAC approval for milk
  - FOSS has ISO approval for cheese (no useable data)
- CEM and FOSS both have AOAC studies for Meat products
  - Good comparison of system expectations

	CEM			NIR		
	Moisture Analysis					
Sample Type	Reference Value (AOAC 950.46)	ORACLE (AOAC 2008.06)	Difference (%)	Reference Value (AOAC 950.46)	NIR (AOAC 2007.04)	Difference (%)
Beef	67.31	67.07	0.24	65.23	62.30	2.93
Pork	60.07	60.05	0.02	61.17	60.51	0.66
Chicken	74.99	74.69	0.30	73.75	73.48	0.27
Turkey	74.67	74.39	0.28	73.85	73.69	0.16
Hot Dog	54.03	53.86	0.17	63.29	62.17	1.12
	Average Difference		**0.20%**			**1.03%**
	Fat Analysis					
Sample Type	Reference Value (AOAC 960.39)	ORACLE (AOAC 2008.06)	Difference (%)	Reference Value (AOAC 960.39)	NIR (AOAC 2007.04)	Difference (%)
Beef	26.56	26.55	0.01	29.30	29.99	0.69
Pork	22.30	22.30	0.00	22.25	21.99	0.26
Chicken	2.91	2.88	0.03	3.17	3.25	0.08
Turkey	1.00	1.03	0.03	1.48	1.89	0.41
Hot Dog	29.79	29.85	0.06	15.39	15.05	0.34
	Average Difference		**0.03%**			**0.36%**
	Protein Analysis					
Sample Type	Reference Value (AOAC 981.10)	Sprint (AOAC 2011.04)	Difference (%)	Reference Value (AOAC 981.10)	NIR (AOAC 2007.04)	Difference (%)
Beef	18.26	18.06	0.20	17.74	18.92	1.18
Pork	16.89	17.26	0.37	17.16	16.71	0.45
Chicken	21.73	22.25	0.52	22.36	22.74	0.38
Turkey	18.17	18.03	0.15	24.47	24.86	0.39
Hot Dog	9.41	9.80	0.39	16.42	15.25	1.17
	Average Difference		**0.29%**			**0.94%**

CEM Dairy AOAC Data

Sample Type		CEM M/S%	CEM F%	Lab M/S%	Lab F%	AOAC M/S%	AOAC F%
Milk	Average	45.60	39.93	45.50	39.94	45.57	39.93
	St Dev	0.04	0.08	0.07	0.08	0.00	0.04
Heavy Cream	Average	45.60	39.93	45.50	39.94	45.57	39.93
	St Dev	0.04	0.08	0.07	0.08	0.00	0.04
Mozzarella	Average	46.03	24.36	46.12	24.38	46.15	24.32
	St Dev	0.15	0.11	0.01	0.05	0.07	0.11
Swiss	Average	39.98	27.93	39.82	27.99	39.96	27.98
	St Dev	0.07	0.15	0.10	0.12	0.17	0.16
Cheddar	Average	36.68	31.32	36.76	31.29	36.76	31.29
	St Dev	0.12	0.11	0.10	0.14	0.05	0.13

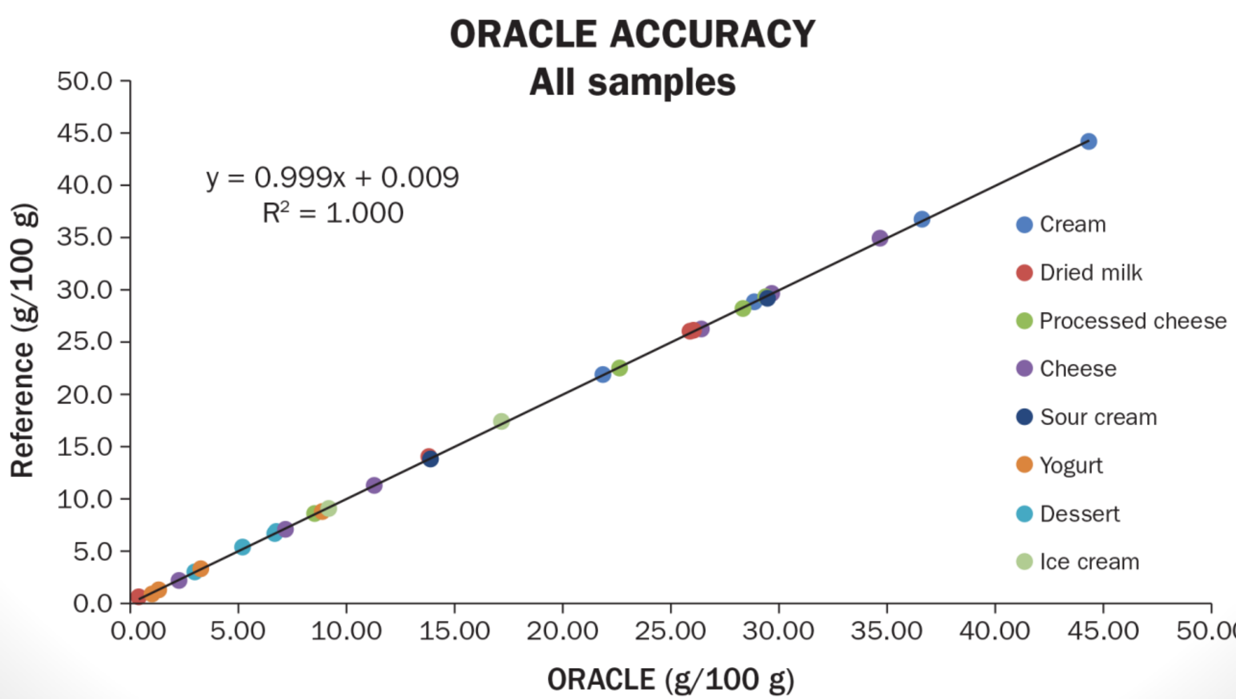
CEM Proven as Accurate

- AOAC data shows that CEM is:
  - 5x more accurate for moisture (0.20% vs 1.03%)
  - 11x more accurate for fat (0.03% vs 0.36%)
  - 3x more accurate for protein (0.29% vs 0.94%)

- Data from AOAC and customers proves CEM is also more accurate for Dairy products
  - Better Accuracy = Better Products = Higher Cost Savings

Further Validation from Actalia

- Actalia is a COFRAC accredited lab in France
  - Validates equipment for the Dairy industry
  - Highly involved in ISO and IDF
    - Seen as “experts” in dairy analysis



NIR calculations

- Validation
  - Cost to build the method calibration
    - 20-50 samples X cost/test for reference X # of components X # of calibrations
    - 20-50 x $50 x 3 = $3,000-7,500/Calibration
    - Or buy premade calibration from FOSS $5,000-7,000
- Annual Maintenance
  - Cost to use the system and maintain accuracy
    - 5 samples x cost/test for reference x # of components x frequency/year x # of calibrations
    - 5 x $50 x 3 x 12 = $9,000/Calibration

Cost of Ownership

	NIR+FT-IR/FT-NIR	CEM
Annual Tests	5,000	5,000
	Calibration Cost	Consumable Cost
1 CALIBRATION	**$9,000**	**$6,000**
4 CALIBRATIONS	**$36,000**	**$6,000**
8 CALIBRATIONS	**$72,000**	**$6,000**

Both prices approximated based on regional/volume pricing differences

- NIR costs based on suggested maintenance of ANN calibrations
  - 3 components (Moisture, Fat, Protein)
  - No reformulations or recalibrations, only typical maintenance
- CEM costs based on consumables for ORACLE
  - 2 components (Moisture, Fat)
  - List price (can be decreased based on purchase quantity)

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FOSS

Application Facts

FOSS ANN meat calibration
- the key to reduced calibration costs

The ANN calibration has a huge advantage compared to other calibration techniques: A very robust calibration can be developed, with no limit as to how many samples can be included in the calibration.

With one ANN calibration it is possible to cover many different products, where you traditionally need to develop and maintain several calibrations. This means reduced calibration development and maintenance costs, as less reference analyses are required.

The purpose of this paper is to show how the ANN-calibration is a superior calibration method and a more cost-effective method compared to PLS.

The content is structured as follows:

- FoodScan measurement principle
- Calibration methods: PLS versus ANN
- The FoodScan ANN calibration for raw meat & meat products
- Case study

calibration – it comes with the FoodScan. It would only be necessary to verify each calibration (for slope & intercept adjustment of the ANN). The total reference analyses costs for verification of the ANN calibration in the example, when four constituents are determined, would be <u>4,800 US$</u> (20 x 4 x 4 x15 US$).

Likewise, the total annual costs of maintaining the 4 ANN versions would be <u>14,400 US$</u> (12 x 5 x 4 x 4 x15 US$).

Based on the example, the difference in number of reference analyses needed, and the related costs for operation of PLS and ANN can be summarised as shown in table 3.

Table 3. Comparison of PLS and ANN – based on example (table 1 and 2)

	PLS	ANN	PLS	ANN	Savings (US$)
	No. of ref. samples		Costs ($)		
Building calibrations					
- Actual building	1400	0	72,000	0	72,000
- Validation	280	80	14,400	4,800	9,600
Annual maintenance					
(monthly verification)	840	240	43,200	14,400	28,800

5. Conclusion

- **Both when establishing as well as in the annual maintenance of the calibrations, there are huge savings when using ANN.**
- **In many cases what the user saves by going from PLS calibrations to ANN can pay for the FoodScan within 1-2 years or even a shorter period.**
- **Particularly where new PLS calibrations have to be built, huge savings are achieved by using ANN instead.**
- **The higher the number of PLS calibrations used, the higher the savings by switching to ANN.**

Dedicated Analytical Solutions

P/N No. 1025682
Issue No. 1
September 2003

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Conclusion vs NIR

1. Better Accuracy
   - Proven by AOAC studies
   - Better Accuracy = Better Process Control = More $$$
2. Less $$$ to maintain
   - Consumables are cheaper than Calibrations
3. Easier to Use
   - Fewer methods, no calibrations, easier sample prep
4. More Universal
   - Same systems used for any product
     - Meat or Dairy, Liquid or Powder, etc

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SMART Trac

Vs SMART Trac II

	ORACLE	SMART Trac II
Direct Analysis	Yes	Yes
Average Test Time	3-4 minutes	3-4 minutes
Method Development	No	Yes
Use with R&D/New Formulations	Yes	No
Footprint (W x D x H)	15.6 x 22 x 14	14 x 14 x 22
Consumables	1-2 pads, 1 Trac film	1-2 pads, 1 Trac film

Method Development

SMART Trac II requires Method development

1. Samples being analyzed must first be tested via reference chemistry
2. Then raw NMR signals for each sample must be analyzed and plotted against their reference result
3. Samples are then separated into different methods based on which signals are linear
4. All future tests are then based on the linear calibration for that method

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Where the ORACLE helps

- Removes the variability of reference testing present in Trac II method development
- Gives users the ability to “blindly” test new or R&D samples
- No need for revalidation of methods after product reformulations
- Reduces the need for sorting through methods to pick the right one
  - May still be present due to variance in moisture parameters, though to a lesser extent

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ORACLE Customers

Global ORACLE Users

- Nestle Foods (#1 food/beverage company)
- JBS (#5)
- Tyson Foods (#6)
- ADM (#7)
- Cargill Meat (#9)
- Kraft Heinz (#10)
- Unilever (#12)
- General Mills (#19)
- Fonterra (#29)
- Conagra (#30)
- Eurofins
- ALS Testing Labs

…and many more

Many chose CEM after having NIR in the past and losing money to bad accuracy & calibrations

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ORACLE Success Stories

- ~200 ORACLEs sold in <2 years
  - Including Eurofins, Silliker, and other testing labs
- Nestle – 11 plants in Mexico
  - Passed validation for ALL Nestle Standards
  - Nestle hosted webinar in July to all Nestle factories
- Sigma Alimentos – 12 plants in Mexico
  - Success at Monterrey R&D, meeting with directors of Quality and Purchasing soon
- Schreiber, Lactalis, Saputo, Bel
  - All Cheese plants using ORACLE, all have plants in Mexico

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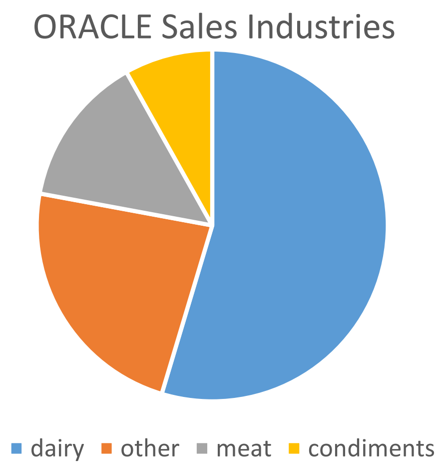
Best Industries

- Processed Dairy (cheese, yogurt, ice cream, etc)
  - Need a fast, accurate test
  - Moisture, Fat, and Protein are all important
  - Need 2 NIR/FT-IR systems (more $ than 2 CEM units)
- Meat Processing
  - Raw Meat – use ProFat for M/F/P in 1 cheap system
  - Cooked Meat – 1 ORACLE method for all products



QUESTIONS?

CEM