

Title: Sodium Bicarbonate Screen in Cookie Dough Specimens**Document Author:** Maran Bush**Date:** 9/8/2014

I. Principle

Baking is a chemical reaction. At 92⁰ Fahrenheit, fats in the dough melt causing the cookie to flatten out. As the dough is heated further, water begins to steam and swell the cookie dough. At 144⁰ Fahrenheit the proteins in the dough uncurl and tangle together, giving the cookie dough stability. At approximately 212⁰ Fahrenheit the water boils out of the dough causing cracks in the surface for the steam to escape. This is accompanied by sodium bicarbonate (NaHCO₃) reacting with acids in the dough which becomes CO₂ gas which, along with the water vapor, create air pockets. As both gases escape through cracks in the dough, the cookie dries out. An excess of sodium bicarbonate will react and swell the dough so much so that as the cookie dries during the baking process, the dough will spread and flatten causing a rippling appearance on the surface of the dough. Excess sodium bicarbonate causes the dough to dry much more quickly in the oven and will thus brown faster than dough with normal amounts of the analyte.

The following reaction occurs: $\text{NaHCO}_3 + \text{H}^+ \rightarrow \text{Na}^+ + \text{CO}_2 + \text{H}_2\text{O}$

This assay is a qualitative screening assay to detect excess baking soda in cookie dough specimens. Results are evaluated by visual interpretation.

II. Safety

- A. Wear appropriate PPE including oven mitts and apron.
- B. Uncooked dough should be treated as potentially infectious. Avoid contact with eyes or mouth.

III. Reagents, Supplies, and Equipment

- A. Reagents
 - 1. Unbleached flour
 - 2. Granulated sugar
 - 3. Light brown sugar
 - 4. Salt
 - 5. Butter
 - 6. Vanilla Extract
 - 7. Baking Soda
 - 8. Eggs
 - 9. Chocolate Chips
- B. Supplies
 - 1. Cookie sheet
 - 2. Spatula
 - 3. Wire cooling rack
- C. Equipment
 - 1. Whirlpool oven

IV. Specimens

Chocolate chip cookie dough specimens should be tested within 24 hours of collection. Store at 2-10 °C. Prior to testing, allow specimens to come to room temperature.

V. Quality Control

- A. A negative, weak positive and positive control should be run with each batch.
- B. To make controls, make dough according to Nestle Tollhouse package.
 - 1. For positive and weak positive controls, set aside 2/3 of the dough. To 1/3, add ¼ tsp baking soda. This is the weak positive control. To the other 1/3, add ¾ tsp. baking soda. This is the positive control.
 - 2. Controls may be stored up to one week at 2-8 °C

VI. Preanalytical Testing

- A. All samples should be accessioned according to ELIS policies and procedures.
- B. Set up cookie sheet template worksheet with positions of controls and sample numbers. See appendix A.

VII. Procedure

- A. Preheat oven to 375 °F for at least 10 minutes.
- B. Using dough scoop, aliquot samples on cookie sheet.
- C. Insert cookie sheet into oven and set a timer for 9 minutes
- D. Remove cookie sheet at 9 minutes +/- 1 minute
- E. Remove cookies from baking sheet immediately and cool on wire rack. Keep cookies in the same configuration they were on the cookie sheet.
- F. Results may be read up to seven days.

VIII. Interpretation and Reporting of Results

- A. Appearance
 - 1. Cookies will flatten and spread during baking in the oven. Normal cookies will be light brown to golden brown in color and are negative for excess sodium bicarbonate.
 - 2. A positive result will show excessive flattening and rippling of the cookie surface. Cookie may also appear dark brown.
 - 3. Weak positive will be visible as rippling that is more noticeable at the edges of the cookie and may appear dark brown at the edges and light brown to golden in the center.
- B. Record results on cookie sheet template worksheet. A second tech must verify results and initial the worksheet prior to entering into ELIS.

- C. Positive and weak positive results should be confirmed with Mass Spectrometry and should be sent to clinical chemistry unit for testing. Positive and weak positive results will have an interpretation comment automatically added to say “Abnormal screening results indicate presence of excess sodium bicarbonate. Confirmatory testing reflexed.”

IX. Limitations

- A. Allow the dough to come to room temperature before cooking. Cold dough may prevent flattening and may mask the rippling appearance of positive or weak positive specimens.

X. References

- A. Original Nestle Toll House Chocolate Chip Cookies. The Very Best Baking <https://www.verybestbaking.com/recipes/18476/Original-NESTLE-C3%89-TOLL-HOUSE-Chocolate-Chip-Cookies/detail.aspx>
- B. Warren, Stephanie. The Chemistry of Cookies. TED talks on YouTube. Visited 9/8/14. <https://www.youtube.com/watch?v=n6wpNhyreDE&noredirect=1>

Appendix A

Sodium Bicarbonate Cookie Sheet Worksheet

Date: _____

Tech: _____

	A	B	C	D
1	Pos			
2	Wk Pos			
3	Neg			

Minnesota Department of Health
Employee Initial Training and Competency Record
Sodium Bicarbonate Screen for Cookie Dough

Employee: _____

Trainer: _____

- **Trainer:** Date and initial the activity AFTER the trainee has demonstrated the necessary understanding, proficiency, or competency. If a level of proficiency does not apply, put N/A in the column.

Activity	Discussed	Observed trainer perform	Performed with Supervision	Observed trainee perform independently
Preanalytical				
Read and understands SOP		N/A	N/A	N/A
Acceptable specimen storage		N/A	N/A	N/A
Acceptable specimen type		N/A	N/A	N/A
Has been trained on use of oven		N/A	N/A	N/A
Preparation of Controls				
Can create cookie sheet template				
Assay Procedure				
Aliquot Cookies onto cookie sheet				
Baking time				
Remove from cookie sheet immediately				
Analysis and Interpretation of results				
Negative				
Positive				
Weak Positive				
Post-run procedure				
Second tech must check and interpret results				
Able to enter into ELIS				
Maintenance				
Clean oven surface each use				
Monthly cleaning procedure				
Yearly cleaning cycle		N/A	N/A	N/A
Troubleshooting and Miscellaneous				
Overbaking may lead to false positive				
Competency/Demonstration of Capability (must fill out associated documentation)				
Competency completed				

Additional training or comments:

References:

1. NCCLS Training Verification for Laboratory Personnel; Approved Guideline GP21-A. Vol. 15 No. 21. December 1995.
2. MDH Laboratory Standard Operating Procedures

*By signing below I, the trainee, attest that training has been completed with the necessary proficiency to perform the procedure(s) as outlined in the associated SOP(s) and that I have had the opportunity to have any questions answered to my satisfaction.

Employee Signature/Date

*By signing below I, the trainer, attest that the employee has the necessary understanding and ability to perform the activities in the associated SOP(s) as outlined above. The employee has been assessed for competency and has been found to be satisfactory or if unsatisfactory, has completed the necessary remedial action and was reassessed as satisfactory.

Trainer's Signature/Date

Supervisor's Signature/Date

Title: Operation and Maintenance of the Whirlpool Oven**Document Author:** Maran Bush**Date:** 9/8/2014

I. Purpose

This SOP outlines the operation and maintenance procedures for the Whirlpool oven, model #WFG510S0AW. Proper care and maintenance is important to produce accurate results for specimens of which this equipment is used. Routine care prolongs the life of equipment and prevents breakage and is an important cost savings measure as well.

II. Safety

- A. Proper use of PPE such as oven mitts and apron are required. Eye protection should be worn when working with specimens that may splatter or easily spill.

III. Equipment and Materials**A. Equipment**

- 1. Whirlpool oven, model #WFG510S0AW

B. Materials

- 1. Easy Off oven cleaner
- 2. Non-scratch pads
- 3. Calibrated thermometer

IV. Processes and Procedures**A. Daily Maintenance**

- 1. Record oven temperature with each use. Temperature should not exceed +/- 5° F for the operating temperature.
- 2. After use, clean surfaces of the oven. Any grease spills inside the oven should be cleaned with mild dish detergent and water. Wipe any soap residue off with a rag with clean tap water.
- 3. All tools used in the assay process such as spatula and baking sheets should be disinfected with mild soap and tap water and be allowed to air dry.

B. Monthly Maintenance

- 1. Spray inside surfaces of oven with Easy Off. Allow to sit for several minutes. Use a non-scratch pad to gently scrub tough stains. Wipe away with a rag soaked in tap water.

C. Yearly Maintenance

- 1. Once annually, run the clean cycle on the oven.

- a. Press the SELF CLEAN button on the control panel above the stove top. Oven will automatically lock when clean cycle has begun.
- b. Allow cycle to run for 4 hours if heavily soiled. Run cycle for 2.5 hours if lightly soiled. Enter the time by pressing TEMP/TIME and use the “+” or “-“ arrow pads to adjust the time.
- c. After cycle is complete and oven has completely cooled, wipe away ash with a damp sponge with tap water.
- d. To stop the cleaning cycle at any time, press the CANCEL button on the control pad. The oven will remain locked if it is too hot and the cooling fan may continue to run.

V. References

- A. Whirlpool oven user manual. Model #WFG510S0AW.
<http://www.whirlpool.com/digitalassets/MLPDF/User%20Instructions%20-%20W10394387.pdf>

Whirlpool Oven Model WFG510S0AW

Month _____ Year _____

Task	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Each Use																															
Record oven temperature (370-380°F)																															
Wash dishes when done																															
Clean surfaces of oven																															
Monthly/Yearly																															
Clean inside of oven with Easy Off (Monthly)																															
Run clean cycle yearly																															
Initials																															

Notes: _____

Reviewed By _____

Method Validation/Verification Approval Form

(For detailed explanation of MDH-PHL validation guidelines refer to MDH SOP G 1.17)

1. Name of person submitting validation plan_Maran Bush_____

2. Test or test modification to be validated
 - a. Reason for study
 - Validation of new laboratory-developed test method
 - Modification of laboratory-developed test method
 - Verification of FDA-cleared test
 - Modification of FDA-cleared test
 - Other (please describe)_____
 - b. Will IRB approval be required/requested for this study? Please explain.
No. This does not involve human subjects.
 - c. Is there a current signed SOP for this method?
 - Yes
 - No
 - d. Is this a quantitative test?
 - Yes
 - No
 - e. Which performance characteristics will be evaluated? Check all that apply.
 - Analytical Sensitivity
 - Analytical Specificity
 - Accuracy
 - Precision
 - Reference Range
 - Reportable Range

3. Determination of Analytical Sensitivity (Limit of detection)
 - a. What sample type(s) will be tested?
 - b. How many samples will be tested?
 - c. How many replicates will be tested? (Recommended minimum number is 3.)
 - d. Unit of Quantitation
 - Colony forming units
 - TCID₅₀
 - DNA copies
 - RNA copies

Other (please describe) _____

- e. Additional experimental details and special considerations.
 - f. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)
4. Analytical Specificity (Interfering substances)
- a. What interfering substances/organisms will be analyzed?
 - b. Experimental details and special considerations
 - c. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)
5. Accuracy (Test reliability)
- a. What will be used as the "gold standard" for comparison?
Toll House Labs has provided samples for validation testing.
 - b. Number and type of positive and negative samples to be tested
20 positive, 10 weak positive, and 20 negative samples will be tested
 - c. Experimental details and special considerations
This is a qualitative assay. Only chocolate chip cookie dough will be evaluated as this assay has not been FDA approved for use with sugar cookie or other types of cookie dough. Toll House created and developed the assay.
 - d. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)
Assay is a visual interpretation of a chemical reaction. Cookies will flatten and spread during baking in the oven. Normal cookies will be light brown to golden brown in color and are negative for excess sodium bicarbonate. A positive result will show excessive flattening and rippling of the cookie surface. Cookie may also appear dark brown. Weak positive will be visible as rippling that is more noticeable at the edges of the cookie and may appear dark brown at the edges and light brown to golden in the center. Results will be evaluated against Toll House Labs results. All must agree 100%
6. Precision (Test reproducibility)
- a. Within run
 - i. Number of samples
9 negative samples spiked with baking soda.
 - ii. Number of replicates (recommended number is 10-30)
Each sample will be run in triplicate.
 - iii. Experimental details and special considerations
Samples will be spiked as follows:
9 samples known to be negative will be spiked with increasing amounts of baking soda (sodium bicarbonate). A pool of dough will be made up according to Toll House Labs instructions for chocolate chip dough. The dough will be divided up into three samples. To

one third, 1/8 tsp baking soda will be added. To the other third, add ¼ tsp. the final third of dough should have ½ tsp of baking soda added.

- iv. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)

Results will be evaluated against the controls. The weak positive control is considered the cut-off value and the assay should show positivity down to the ¼ tsp spiked specimens. Replicates will be expected to agree 100%.

b. Between run

- i. Number of samples
9 negative samples spiked with baking soda
- ii. Number of replicates (recommended number is 10-30)
Each sample will be run in triplicate.
- iii. Experimental details and special considerations
Same protocol will be follow as for within run precision. Samples from the batches created from the within-run precision will be set aside to run the next day by a trained technologist.
- iv. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)
Same as within run-precision. Replicates will be expected to agree 100%.

c. Day to day

- i. Number of samples
N/A (same as between run)
- ii. Number of replicates (recommended number is 10-30)
- iii. Experimental details and special considerations
- iv. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)

7. Reportable Range (for quantitative test only)

- a. Number of samples
- b. Number of replicates
- c. Experimental details and special considerations
- d. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)

8. Reference Range (for quantitative test only)

- a. Number of samples
- b. Number of replicates
- c. Experimental details and special considerations
- d. Data evaluation and acceptance criteria (How will the data be evaluated? What statistical methods will be used? What are the acceptance criteria?)

Verification of Sodium Bicarbonate Screen in Cookie Dough Specimens

Submitted by: Maran Bush

Date: 9/9/14

Associated SOP: QA 1.0 Sodium Bicarbonate Screen in Cookie Dough Specimens

I. Summary

This assay is an important screening tool for excess sodium bicarbonate in cookie dough. Submitters rely on these results to assure a quality, delicious cookie.

II. Performance Data

A. Accuracy (Reliability)

		Toll House Labs		
		Positive	Weak Positive	Negative
Our Lab	Positive	20	0	0
	Weak Positive	0	10	0
	Negative	0	0	20

All samples matched the results expected from Toll House Labs. 100% agreement meets the performance requirements.

B. Precision

1/8 tsp spike	1/4 tsp spike	1/2 tsp spike
Pos, Neg, Neg	Pos, Pos, Pos	Pos, Pos, Pos
Neg, Neg, Neg	Pos, Pos, Pos	Pos, Pos, Pos
Neg, Neg, Neg	Pos, Pos, Pos	Pos, Pos, Pos

One sample for the 1/8 tsp spike showed positivity. The samples were run in triplicate and expected to agree 100%. The 1/8 tsp spiked samples failed to agree 100% which was expected. The 1/4 tsp spikes samples agreed 100% which was the cut off value of the control.

III. Conclusion:

Accuracy and precision met the acceptance criteria and this assay can be reliably used to screen for excess baking soda in chocolate chip cookie dough. A confirmation should be reflexed to confirm and quantitate the excess sodium bicarbonate.

IV. References:

A. QA 1.0 Sodium Bicarbonate Screen in Cookie Dough Specimens

B. Original Nestle Toll House Chocolate Chip Cookies. The Very Best Baking <https://www.verybestbaking.com/recipes/18476/Original-NESTL%C3%89-TOLL-HOUSE-Chocolate-Chip-Cookies/detail.aspx>