DEGREE DAYS and COLD CHAIN

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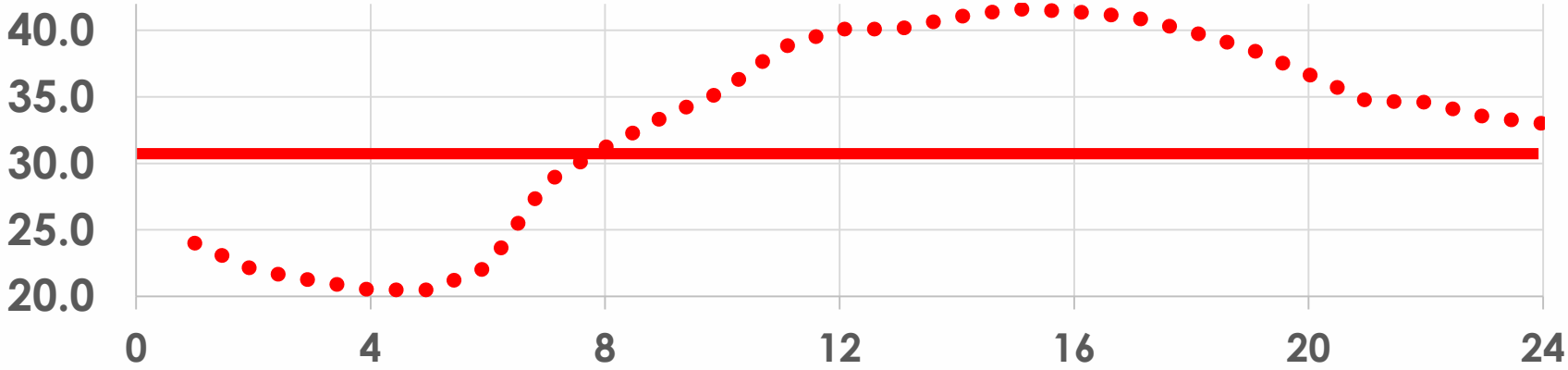
INTRODUCTION
EFFECTIVE COLD CHAIN VALIDATION

- South African Standards of Practice
  - best achieved
    - validation runs carried out
      - simulation-based ambient conditions
        - » ambient temperature conditions mimicked in the validation laboratory
      - using a limit-testing approach
        - » validation runs ambient temperature
          - hottest probable summer conditions
          - coldest probable winter conditions
            - in operational footprint

INTRODUCTION
VALIDATION DIFFICULTIES I

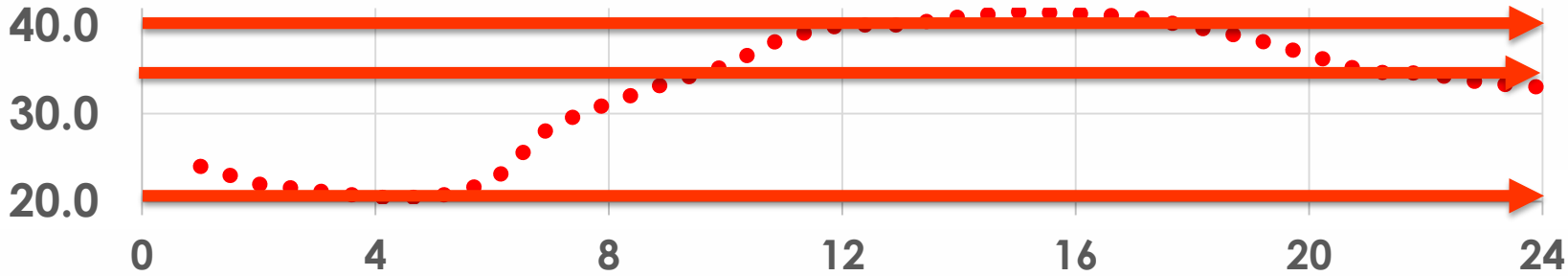
- Simulation based validation
  - limited resources to mimic
    - diurnal temperature variation



  - with non-programable incubators
  - only single temperature testing is possible
    - » results in sub-optimum validation

INTRODUCTION
VALIDATION DIFFICULTIES II

- Limit Testing
  - Selection of justifiable ambient temperatures
    - Maximum temperature
      - only applicable for a short period of time
        - » over-estimation of summer ambient
    - Minimum temperature
      - » under-estimation of summer ambient
    - Average temperature
      - Depending on daily temperature distribution
        - » over or under-estimate summer ambient



INTRODUCTION

DEGREE DAYS (DD_x)

- Architectural measure utilising
  - approximation of area under the curve
    - time temperature curve
  - how much (in degrees)
  - how long (in days)
    - ambient temperature was
      - above or below
        - a specific base temperature level
  - used to model the relationship
    - energy transfer
    - ambient air temperature
  - application in cold chain calculations

INTRODUCTION
DD_x and COLD CHAIN CALCULATIONS

- Validity of derived formulae
  - dependant on relationship between
    - duration (DUR)
      - » time products are maintained within specification
    - degree days (DD_x)
      - » energy measure of ambient temperature
  - Derivation of proposed formulae
    - Direct Variation Equation
      - » $DUR \propto DD_x$
      - » $DUR = k * DD_x$
      - » k = constant

AIM of the STUDY

SANBS

- Study carried out in an attempt to
  - Define the relationship between
    - duration (DUR)
    - degree days (DD_x)
  - Develop valid formulae for metrics
    - useful in the
      - » development
      - » validation
        - Cold Chain Systems

MATERIALS and METHODS I

- Historical temperature records
  - hourly ambient temperatures
  - 5 Freestate and Northern Cape Branches
  - South African Weather Service (SAWS)
    - » 2013 to 2015
- Determine base 21 Degree Days (DD_{21})
  - warmest
    - » highest 24 hour average temperature
  - coolest
    - » lowest 24 hour average temperature
  - days of the 3-year period
  - SANBS operational footprint

MATERIALS and METHODS II

- Whole Blood (WB) validation runs
  - South African National Blood Service (SANBS) protocols
    - » summer ambient simulations 40ºC
    - » winter ambient simulations 10ºC
  - Continuous measurement
    - » of time and temperature
    - » the I-button System
- Data used to prepare
  - » time/temperature curves
  - » and .....

MATERIALS and METHODS III

- Novel Cold Chain Metrics
  - Corrected Duration[cDUR (hours)]
    - » DUR at one ambient temperature converted to DUR at another ambient temperature
  - Optimum Validation Temperature [T_{valid}(ºC)]
    - » optimum simulation ambient temperature for validation runs
  - Efficacy Index [EI (%)]
    - » Cold Chain efficacy metric for comparative use

RESULTS

- Regression Analysis
  - Excel 365 stats functions- Significance P<0.05
  - Duration vs Degree Days
    - n=19, r=-0.77, P=0.00
- S A Weather Service Data
  - Hottest day in Upington 18th Dec 2015
    - Average 33.1º, Max 41.6º, Min 20.5º, DD_{21} 12.1
  - Coldest in Bethlehem 8th July 2014
    - Average -0.1º, Min 9.2º, Min -9.0º DD_{21} -21.1

DISCUSSION I

VALIDITY and USE of NEW METRICS

- Significant correlation between
  - Duration and Degree Days
    - validated the use of the
      - » Direct Variation Equation
        - calculation of the novel metrics
  - Usefulness of these metrics
    - validation of a newly developed
      - » illustrated by
        - whole blood cold chain system
        - prior to new metric availability
          - errors in development and validation

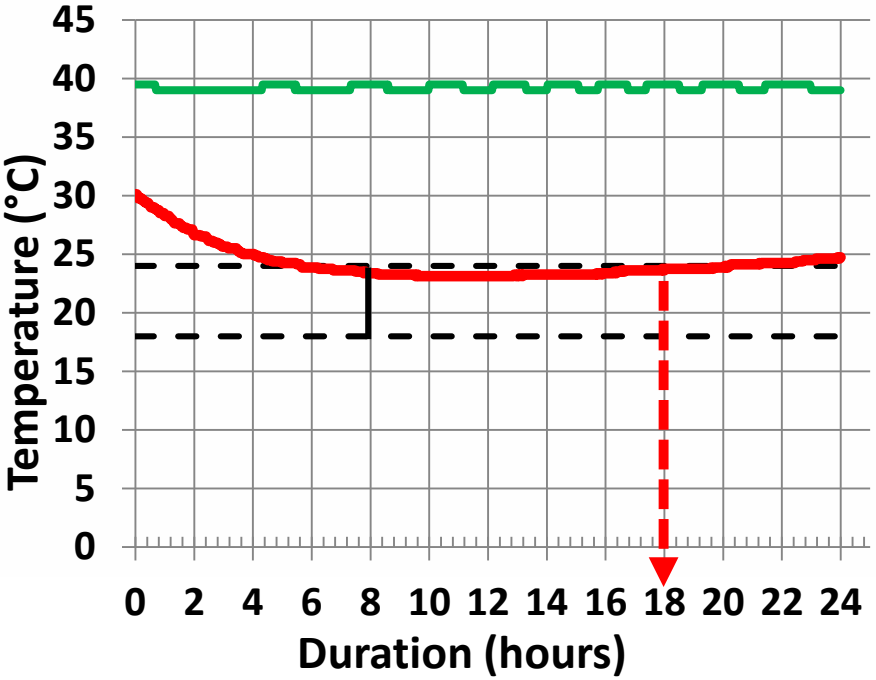
DISCUSSION II
WHAT SHOULD HAVE HAPPENED

- Prior to system development
  - calculation of
    - validation run ambient temperature
  - **Degree Days**
    - DD_{21} = ***Average 24hour Temperature - Base***
      - » *Summer (hottest day)= 33.1 - 21* = **12.1**
      - » Winter (coldest day) = 0.1 – 21 = **-21.1**
  - **Optimum Validation Temperature**
    - $T_{valid} = DD_{21} + Base$
      - » Summer = (12.1 + 21) = **33.1ºC**
      - » Winter = (-21.1 + 21= **-0.1ºC**

DISCUSSION III
WHAT ACTUALLY HAPPENED

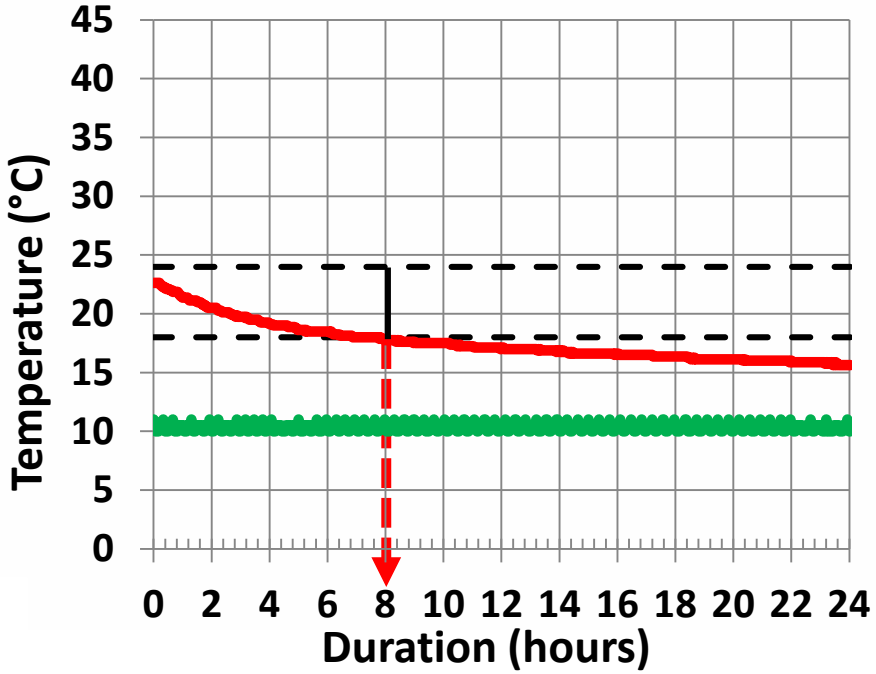
- Original validation temperatures
  - "educated guess"

Summer 40ºC



DURATION 18 hours

Winter 10ºC



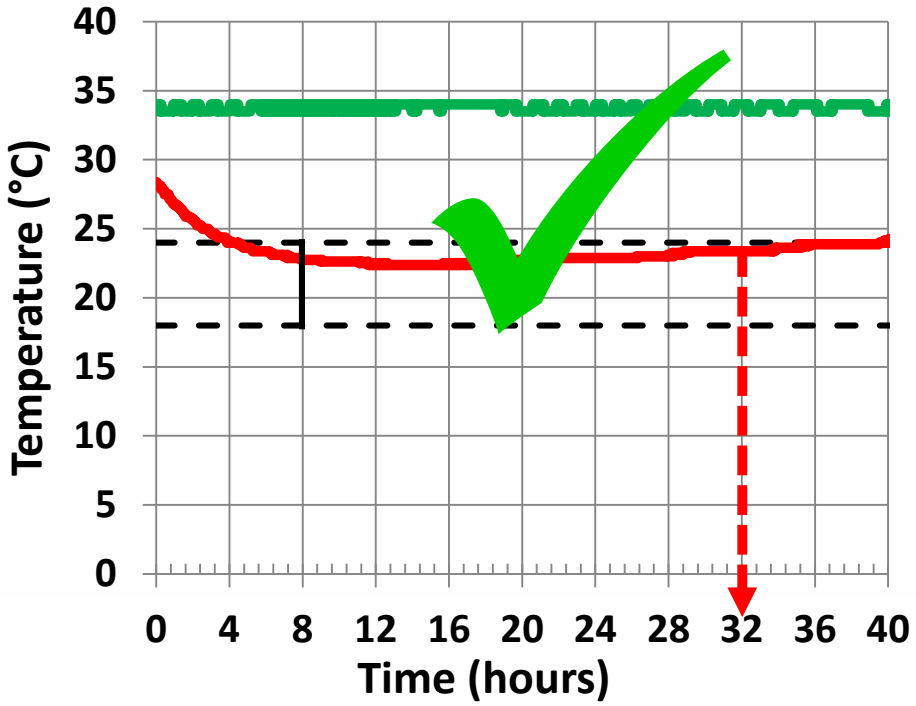
DURATION 8 hours

DISCUSSION III
WHAT SHOULD HAVE HAPPENED

– Calculated validation temperatures

- **Optimum Validation Temperature**

Summer 33ºC



DURATION 32 hours

Winter 0 ºC

- Validation at10ºC
  - 8 hou uration

- Development Fault back to the drawing board

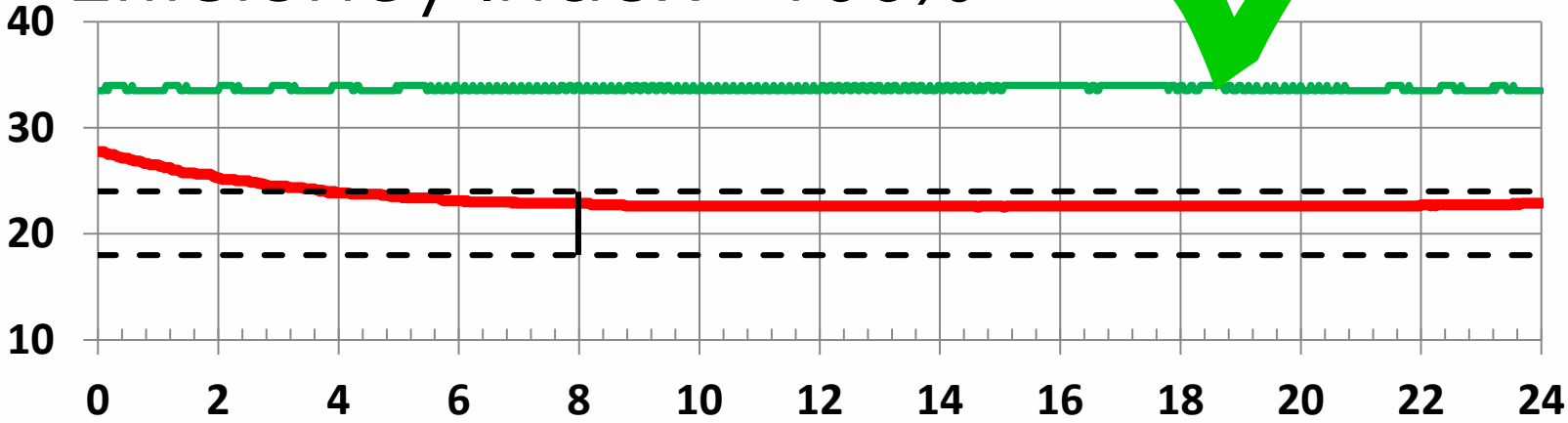
DISCUSSION IV
OTHER METRICS

- **Corrected Duration (cDUR (hours))**
- ***= [(DD_{21} 40° C) ÷ (DD_{21} 33° C) * DUR1***
  - Whole Blood Validation
    - » actual duration at 40ºC = 18 hours
    - » calculated duration at 33ºC = 29 hours
    - » actual duration at 33ºC = 32 hours
      - Variance of 9.3%
- **Efficacy Index (EI (%))**
- ***=((4*(amb – base)) ÷ ((mean prod temp – base)*24))***

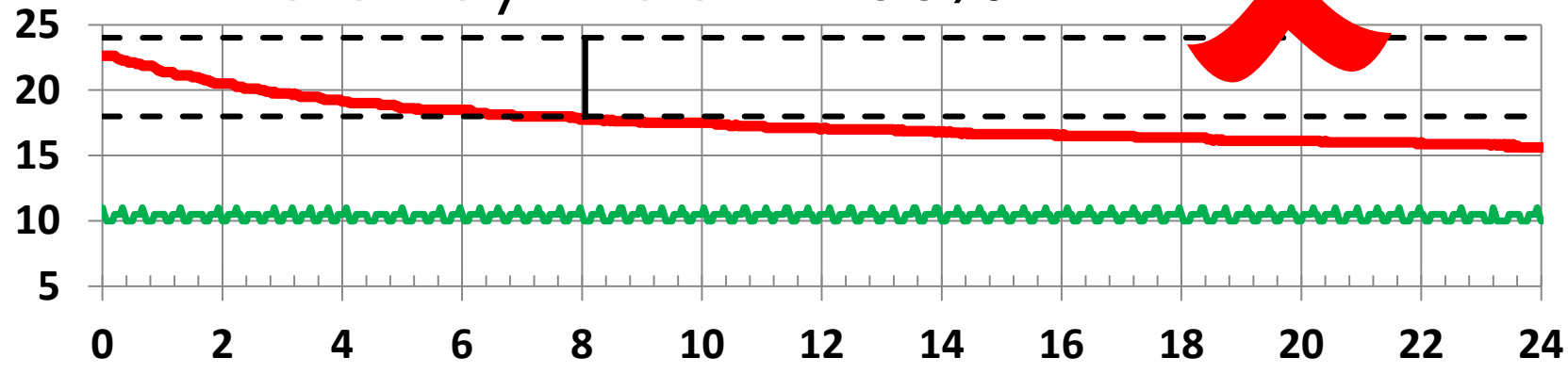
DISCUSSION IV

EFFECIENCY INDEX

- Whole Blood Validation (33ºC)
  - Efficiency Index= 106%



- Whole Blood Validation (10ºC)
  - Efficiency Index = 63%



CONCLUSION

- The results indicate
  - significant linear relationship between
    - Duration and Degree Days
      - » supports the calculation
        - valid novel metrics
          - Corrected Duration
          - Efficacy Index
          - Optimum Validation Temperature
  - Appear to be of value
    - development and validation
    - Cold Chain Systems

RECCOMMENDATIONS

- SAWS data be updated
  - accurately reflect
    - historical HOTTEST DAY
    - historical COLDEST DAY
- Duration vs Degree Days
    - Relationship be confirmed
- Metrics be validated
  - use and scrutiny in the future
    - development of new systems
    - re-validation of current
      - » cold chain systems


Thank you